EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	:	MDL NO. 2875
	:	HON. ROBERT B. KUGLER
THIS DOCUMENT APPLIES TO ALL CASES	:	

- CONFIDENTIAL INFORMATION -
SUBJECT TO PROTECTIVE ORDER

- - -

September 14, 2021

- - -

VOLUME I

Videotaped remote deposition of LEE-JEN WEI, Ph.D., taken pursuant to notice, was held via Zoom Videoconference, beginning at 9:08 a.m., on the above date, before Michelle L. Gray, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

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I N D E X

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Testimony of:

LEE-JEN WEI, Ph.D.

By Mr. Nigh 12

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E X H I B I T S

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DEPOSITION SUPPORT INDEX

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Direction to Witness Not to Answer
PAGE LINE
None.

Request for Production of Documents
PAGE LINE
None.

Stipulations
PAGE LINE
None.

Questions Marked
PAGE LINE
None.

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THE VIDEOGRAPHER: We are now on the record. My name is Judy Diaz. I am a legal videographer for Golkow Litigation Services.

Today's date is September 14, 2021, and the time is 9:08 a.m.

This remote video deposition is being held in the matter of Valsartan, Losartan, and Irbesartan Products Liability Litigation MDL.

The deponent is Lee-Jen Wei Ph.D.

All parties to this deposition are appearing remotely and have agreed to the witness being sworn in remotely.

All counsel will be noted on the stenographic record.

The court reporter is Michelle Gray and will now swear in the witness.

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... LEE-JEN WEI Ph.D., having been first duly sworn, was examined and testified as follows:

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EXAMINATION

- - -

BY MR. NIGH:

Q. Good morning. My name is Daniel Nigh, and I represent the plaintiffs.

Dr. Wei, could you please state and spell your name, your last name?

A. Name is W-E-I, Wei. First name Lee-Jen, L-E-E, hyphenation, J-E-N.

Q. Okay. Let's take a look at LP-1556.

(Document marked for identification as Exhibit Wei-1.)

BY MR. NIGH:

Q. That's how I'm going to call them out, Doctor. And then the videographer is growing to put the document up on the screen. This will be marked as Exhibit -- Exhibit 1.

Okay. This is -- Doctor, this is your deposition here. Have you seen this before today?

A. Yes, sir. Would you mind blow up a little bit?

Q. Sure.

A. Thank you. Yeah. Thank you.

Q. Yeah. And let's take a look at the third page where it shows exhibit. And let's go ahead and blow up document requests, and the first couple -- the first couple requests.

Do you see this here? On the third page of this deposition there was an attachment called exhibits.

Do you see this?

A. Yes, sir.

Q. And did you review this request for exhibits -- or request for

documents I mean?
A. Yes, I did, with the lawyer.
Q. And you provided all of the documents that you had that were responsive to this to your lawyer?
A. As much as I can.
Q. Okay. Let's take a look at LP-1600.
(Document marked for identification as Exhibit Wei-2.)
MR. NIGH: This will be marked as Wei Exhibit Number 2.
BY MR. NIGH:
Q. Let's blow up the first part of this. It says, "Defendants' responses and objections to plaintiffs' notice of videotaped deposition."
Do you see that?
A. Yes.
Q. And let's take a look at the second page. Here we ask for copies of all invoices. Let's look at Number 1, the documents.

"Copies of all invoices" -- right at the very beginning -- "for work performed in connection with any consultation or expert work provided for on behalf of any defendant."
Do you see that?
A. Yes, sir.
Q. And on the second page, there are some objections.
The second page says, "Subject to" -- or the next page says, "Subject to" --
MR. NIGH: If we can blow that part up.
BY MR. NIGH:
Q. "Subject to and without waiving these objections and any of the foregoing general objections, defendants will produce invoices in advance of Dr. Wei's deposition."
Do you see that?
A. Yes, sir.
Q. Okay. Do you believe that you provided all of your invoices for

this case?
A. Yes. There is only one invoice.
Q. Okay. Let's take a look at the second request. It says, "Copies of any notes, written or electronic, reflecting consulting or litigation work that has not been documented in invoices."
A. Well, the only thing I have is a draft of my report. So that's about it.
Q. Okay. All right. Let's take a look at Number 3.
Let me ask you this, when you would be reviewing -- when you would review literature articles, would you keep notes on those literature articles or would you keep notes anywhere, like in a Word document?
A. No, sir.
Q. So you would only put your notes into the draft of the report?
A. Sometimes I just highlight

the papers I'm reviewing.
Q. You would only highlight papers that you're reviewing, but you wouldn't write anything on those papers?
A. I don't think so for this case.
Q. Okay. Number 3 says, "Copies of any notes or other documentation, including PowerPoints for any presentations, seminars, or classes given by Dr. Wei with regard to the risks and benefits of any angiotensin blockers or nitrosamines."
Did you have any notes or other documentation for any presentations, seminars, or classes --
A. No, sir.
Q. -- regarding ARBs or nitrosamines?
No? Okay.
Do you recall giving any presentations for ARBs or nitrosamines?
A. No, sir.
Q. Okay. Taking a look at

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Page 4 -- Number 4. Sorry.
"Copies of any documents or articles relied upon for the opinions set forth in the report served."
At the bottom it says, "Subject to and without waiving these objections and any of the foregoing general objections, defendants will produce a copy of all electronically available documents identified on Dr. Wei's list of materials considered prior to his deposition."
Did you also provide the highlighted studies, studies that you would put -- that you would highlight to your attorneys?
A. Yeah, I remember I send two articles with highlighted portions to the lawyers.
Q. Are there only two articles that you ever highlighted?
A. Yeah, pretty much.
Q. Okay. What are those two articles?

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A. I don't remember. I send it to the lawyers last week.
Q. Okay. Let's take a look at Number 5. "Copies of any documents or articles reviewed in connection with the report thereto, whether or not listed in the report."
And the answer at the end says, "Subject to and without waiving these objections and any of the foregoing general objections, defendants will produce a copy of all electronically available documents identified on Dr. Wei's list of materials considered."
How did you pull together your -- these electronic documents? What's the process that you undertook to pull these together in order to respond to these requests?
A. Well, first, I got a list of references that are recommended by the lawyers. And I downloaded to my computer, and as a PDF file. And that's -- from there, I just used that

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copies and reviewed papers, documents and et cetera.
Q. Okay. So I think you said you got a list of references from the lawyers?
A. Yeah. It is a listing. It actually is all the files. They send me a website. I can just download it easily.
Q. Okay. Was that like a DropBox or some kind of platform where you could download studies and internal documents, that sort of thing from that file?
A. Probably it's like a DropBox. It's very convenient, actually. I find it very nice.
Q. Okay. And is that where you pulled all of your literature that you reviewed in this case?
A. Yes.
Q. Okay. So all the literature that you reviewed in connection with your report was provided to you by the defense

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attorneys?
A. Yeah. There's only one thing that I did make a quick search through the Google about other studies directly related to impurity of valsartan product.
Q. Did you find any additional documents that you reviewed with that Google search?
A. I did not.
Q. Okay. So if I understand this correctly, you did a quick Google search looking for anything related to the impurity of the valsartan product, and you didn't find any additional documents that you reviewed with that Google search, correct?
A. That's correct, sir. If I may just add in one sentence. For all other studies, publications, when I read Dr. Madigan's report, if Dr. Madigan is citing some reference or publication, was not on the list, I would ask the lawyer to send to me. That's what I did once to

the lawyer.
Q. Okay. So if I understand you correctly, you also looked at Dr. Madigan's report, and there was one study that you didn't see in that DropBox that you asked the defense lawyers to provide to you?
A. Correct.
Q. Okay. So all of the literature that you reviewed was provided to you by your lawyers, correct? I mean, by the defense lawyers, correct?
A. Yes.
Q. Okay. Let's take a look at Number 6. "Any illustrations, PowerPoints, images, charts, tables or demonstrative exhibits that may be used by or with Dr. Wei in connection with the Daubert hearing or trial testimony in this litigation."
Other than what's contained in your expert report, you don't have any other illustrations, PowerPoints, images, charts or tables or demonstrative

exhibits that you're expecting to use, correct?
A. Not yet.
Q. Not yet?
A. Yeah, so I think in my report I clearly state that maybe in the future we may actually create a PowerPoint presentation or tables or graphic display.
Q. Do you have any idea what those tables or graphic displays would look like --
A. No.
Q. -- at this time? No?
A. Not yet.
Q. Okay. So you understand that I would have no ability to question you regarding those demonstrative tables or those charts here today if they're not contained in your expert report and you don't even know what they would be, correct?
A. They don't exist yet.
Q. Right. So I wouldn't have

ability today to ask you questions today regarding those charts or tables, correct?
A. Fair enough.
Q. I'm sorry. What was your answer?
A. I said fair enough. What you're saying, yes.
Q. Okay. Let's take a look at Number 7. Number 7, "Documentation of any research grant the witness has been provided to study any angiotensin blockers, nitrosamines, and health effects possibly related thereto."
You haven't received any research grants related to ARBs, correct?
A. Correct.
Q. And you haven't received any research grants related to nitrosamines, correct?
A. Correct.
Q. Okay. Take a look at Number 8. "Documentation" -- "Documentation of any research the witness has performed

with regard to any ARB or nitrosamine."
You haven't done any independent research -- other than in connection with your expert opinions here today, you haven't done any independent research regarding ARBs or nitrosamines, correct?
A. Sir, let me make sure. This is a pretty broad question. For the safety or impurity of valsartan, I haven't done anything except this report.
But if you're talking about in general, the research regarding the ARB, I did know something about it because I work closely with Brigham and Women's Hospital at Harvard cardiologists for many years.
Q. Okay. Have you performed research related to ARBs?
A. I believe in some of my papers, I utilize some research papers regarding to ARB, ACE inhibitor, beta blockers in the past.
Q. Okay. Have you done any

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research regarding nitrosamines?
A. I don't think so.
Q. In terms of ARBs, what would be the extent of your research?
A. Well, mostly we are really interested into combining ARB and ACE inhibitor, see if we can get a better treatment effect from this combination compared with monotherapy, for example ACE inhibitor or ARB alone.
Q. Other than measuring whether or not you would get a better effect when combining ARB and ACE inhibitor compared to ACE inhibitor or ARB alone, have you done any other research regarding ARBs?
A. I don't know exactly. But sometimes I writing for physical papers, I may cite it in some papers related to ARB publications, mostly related to efficacy. For example, reduced the hospitalization, reduced the cardiovascular death. That's most of my statistical papers are about.
Q. Okay. If I understand you

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correctly, you have cited to papers and ARB publications, in large part as ARBs are medications taken for hypertension and help to reduce hospitalizations and reduce cardiovascular death; is that correct?
A. Yes, sir, for heart failure patients. Mostly for heart failure, not for blood pressure problem.
Q. Mostly for heart patients?
A. Heart failure.
F-A-I-L-U-R-E.
Q. Oh, heart failure. Okay.
And in terms of those patients, if they were to stop taking their ARB without any substitute, then at the time that they're stopped taking the ARB without any substitute, they would lose the benefit of it helping to reduce hospitalizations, reduce cardiovascular death, correct?
A. I don't know. I'm not a clinical person. I cannot make -- either way.

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Q. Let's take a look at nine.
Nine asked for, "Copies of any documents, including protocols or information about medication side effects, available to the witness from any hospital or academic institution where he has worked, had an appointment, or had privileges which set forth information related to the risks and benefits of any ARB or nitrosamine."
Do you see that?
A. Yes, sir.
Q. Now, you didn't have any copies of documents, including protocols or information about medication side effects, correct?
A. I don't.
Q. Okay. Number 10, "Any documents or other communications the witness has received from any person or entity with regard to nitrosamine impurities in any ARB or other drug.
So other than the documentation provided to you by your

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counsel, you didn't have any other documents or review any other documents from any other person or entity regarding nitrosamine impurities in ARBs, correct?
A. That's correct, sir. The only thing that I'm really concerned is about all the publications, documents cited by Dr. Madigan in his report.
Q. Okay. Number 11, "Any communications from the witness to any person or entity with regard to nitrosamine impurities in any ARB or other drug, outside of communications through counsel."
So other than -- other than defense counsel, you haven't had any other communications with any other witness or any other person regarding your work here regarding nitrosamine impurities and ARBs, correct?
A. Correct.
Q. Okay. Number 12, "Any textbook referenced by the witness in forming his opinions."

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You didn't rely on -- did you rely on any portion of any textbook to form your opinions here today?
A. Yes, sir. There is one book --
Q. Which?
A. -- by David DeMets, Clinical Trials. I cited in my report.
Q. Which textbook was that again?
A. Do you have a list of references? I can point it to you.
Q. We'll come back to that.
A. Furberg. I think the first author is if Furberg, I think.
Q. We can take this down. We'll take a look at your expert report.
This is LP-1557.
(Document marked for identification as Exhibit Wei-3.)
MR. NIGH: This will be marked as Exhibit Wei-3.
BY MR. NIGH:

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Q. Do you see this here? This appears to be your expert report that you prepared for this litigation, correct?
A. Yeah. May I see my signature, on -- toward last -- if you don't mind.
Q. Sure. Let's take a look at Page 24.
A. Yes, sir.
Q. Is that your signature?
A. Yes, sir.
Q. The date of this is August 2, 2021, correct?
A. Yes, sir.
Q. Now, you understand that one of the purposes of this expert report is to put us on the other side, you know, on the plaintiffs' side, plaintiffs' counsel, on notice of your opinions, correct?
A. Yes, sir.
Q. And if you don't include certain opinions in this expert report, then we would not be provided notice of

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those opinions, correct?
A. I don't know. Whatever you say. I don't understand the rules anyway, so I leave it up to you.
Q. Okay. Let's take a look at Number 11 on Page 5. And this says "Assignment."
And under assignment, it says, "I have been retained by defendants to provide an expert opinion in the litigation styled In Re Valsartan Products Liability Litigation. Specifically, I was asked by counsel for defendants to review and assess the opinions presented by David Madigan, Ph.D., who submitted an expert report on behalf of plaintiffs analyzing the results from the Dietary and Occupational Studies to infer potential risk of carcinogenicity of ND" -- I think you meant NDMA, as opposed to NDME, right?
A. Yes. It should be NDMA.
Q. Okay.
-- "of NDMA or NDEA

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impurities in valsartan and to provide my own assessment of those issues."
Correct?
A. Yes, sir.
Q. Okay. And so is it your understanding -- did you only become involved after Dr. Madigan had completed his expert report?
A. I believe so. I got Dr. Madigan's report from the lawyer.
Q. Okay. And so when you started, you had a completed report by Dr. Madigan, correct?
A. Correct.
Q. Now, this isn't the first time that you've been on the opposite side of Dr. Madigan, correct?
A. It's the first time, you're saying, sir?
Q. Right. This isn't the first time. This is not the first time you've been on the opposite side of Dr. Madigan, correct?
A. No. I don't know how many

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times.
Q. Okay.
A. I don't recall how many times we were on opposite sides.
Q. Well, that's what I'm about to ask you. What are the other times -- what other litigation can you remember being on the opposite side of Dr. Madigan?
A. I believe at least we had Celebrex --
Q. Okay.
A. An injury case, and also security case. Dr. Madigan was on the wrong side. And I'm sorry. That's not politically correct. I just -- he is on the plaintiff's side.
Then you have Taxotere case still ongoing. Dr. Madigan is on the opposite side.
I believe there are other cases, sir. I just don't remember.
Q. So the ones that you can remember -- I'll make sure that I've got

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this correctly. The ones that you can remember that you've been on the opposite side of Dr. Madigan, there's Taxotere which is -- that's a litigation that's still ongoing, correct?
A. Correct.
Q. There's Celebrex. Now, that's a litigation that you got involved in more than ten years ago, correct?
A. Yeah. Correct.
Q. You said there's a securities case?
A. Yeah, it's actually economic loss, in some way. This -- the investor, they claimed they lost the money, whatever it is, because the safety issue about Celebrex.
Q. I see. Okay. And other than those three, I think you mentioned one or two more. What were the other two -- or the other ones?
A. No, I -- I don't remember other. I don't remember, sir.
Q. I see. So you just remember

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those three?
A. Yeah, that's as far as I can tell. But, you know, maybe there are more.
Q. Okay. Now, who first reached out to you in this case? Which -- how was that contact made to you?
A. It's defendant lawyers.
Q. Okay. Defending lawyers. Which defending lawyer reached out to you?
A. Steve -- Steven, right? Steven.
Q. Steve Harkins?
A. Yeah. Hartley.
Q. Okay. So Steve Harkins reached out to you?
A. Yes, sir.
Q. Have you ever worked with Steve Harkins on any other litigation?
A. No, sir.
Q. Okay. All right. Let's take a look here. You were asked to

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analyze the opinions by Dr. Madigan. And so a lot of your report will be basically a response or criticism of Dr. Madigan's report, correct?
A. Yes, sir.
Q. And then you put, "and to provide my own assessment of those issues."
Do you see that?
A. Yes, sir.
Q. Now, what do you mean -- other than responding or criticizing Dr. Madigan, what did you do in terms of providing your own assessment?
A. For example, I made a comment about observational studies issue. And I provide the valsartan studies. And Dr. Madigan didn't mention it at all in his report.
Q. Okay. So those are a couple of examples where you say you made a comment about observational study. And then you reviewed the valsartan studies and gave commentary on the valsartan

studies, right?
A. Yes, sir.
Q. Other than those two examples, is there any other original work that you did that wasn't just a response or criticism to Dr. Madigan's report?
A. Well, Counsel, if you don't mind, maybe later on we can go through my report. We probably can pick up something I can share with you what are the -- actually from my own opinions, which are not. But right now, that's the only two things that I remember.
Q. Okay. And we will go through them further. I'm just trying to, you know, lay some structure here first.
So other than those two, those are the only two opinions that you can think of that are original opinions as opposed to responding to Dr. Madigan?
A. Yeah. At this point, yes.
Q. Okay. Now, Dr. Madigan

calculated lifetime cumulative exposures.
Did you understand that?
A. Well, I understand it. But I disagree with it.
Q. I understand that you disagree. But do you understand that he was calculating cumulative exposures?
A. Yes.
Q. Okay. Now, you didn't provide any of your own calculations on cumulative exposures, correct?
A. No.
Q. And you haven't done any of your own calculations on cumulative exposures, correct?
A. No.
Q. And you didn't provide any criticisms of his calculations. You provided criticisms about extrapolating those calculations, but you didn't provide any criticisms on the calculations themselves, correct?
A. Well, I think that his basic methods he rely to calculate exposure

dosing level is flawed. I don't think I even needed to worry about his mathematical calculation.
Q. Right. And when you said his basic methods, you mean you have concerns about him extrapolating those results to NDMA and valsartan, correct?
A. More than that, sir. Even within the dietary studies, I have a great concern about his conclusion, even without extrapolate the results from a dietary study to valsartan.
Q. Okay. And that may be being able to rely on the findings in the dietary study itself, correct?
A. Correct.
Q. But in terms of the calculations that he did, you didn't have any criticisms of the calculations, just how he would be able to use those calculations, correct?
A. Well, I don't have data to verify exactly the number he calculate. But I understand his mathematical

formula. But that doesn't mean that his calculated values are valid. I don't know that part because I don't have the data.
Q. Okay. I understand. You didn't -- you didn't provide any criticisms on the math that he did, correct?
A. The formula he used.
Q. Right. You didn't provide any criticisms on the math he did -- he completed, or the formula that he used to complete -- complete those calculations of lifetime cumulative exposures, correct?
A. See, let me answer this question to you, sir. I have no problem if he defines so-called a mean value of this exposure time, okay, mathematically. But I am not so sure that quantity can be utilized to define the threshold of value, beyond that value we have high risk of cancer incidence. I disagree with that, the application.

But, sir, if you ask me if his mathematical formula to calculate what he thinks is okay, I say, yes, his mathematical formula is very simple. Everybody can understand it.

Q. Now, you just said, "I have no problem if he defines a mean value of this exposure time, okay, mathematically. But I am not so sure that the quantity can be utilized to define the threshold value, beyond that value we have high risk of cancer incidence."

So you disagree with that application.

Now, that opinion is nowhere to be found in your report, correct?

A. Correct.

Q. And so for the first time here today, you're giving that criticism, correct?

A. Well, that's my concern. I don't mean to put in the report, because basically I don't even think the way he derived this lifetime exposure level is

correct. So I don't even bother to go in saying, "Your calculation is misleading, even though mathematically it's correct."

MR. NIGH: Okay. Let's take a look at LP-1558.

(Document marked for identification as Exhibit Wei-4.)

MR. NIGH: Let's blow up that first part. This will be marked as Exhibit 4, Wei Exhibit 4.

BY MR. NIGH:

Q. And you see the top part says, "NDMA-Contaminated Valsartan, David Madigan, Ph.D." And it shows his signature.

Do you see that?

A. Yes, sir.

Q. And this is the report that you were speaking about in Number 11 in terms of your report, your assignment, was to review this report and provide your response or criticisms of this

report, correct?

A. Yes, sir.

Q. Okay.

MR. NIGH: Let's take a look at LP-1576.

(Document marked for identification as Exhibit Wei-5.)

BY MR. NIGH:

Q. And can you see that this is your invoice?

A. Yes, sir.

MR. NIGH: Let's go ahead and blow up that top part, the very top part there, right.

BY MR. NIGH:

Q. And it starts out with Bluenull LLC, and it gives an address there.

Do you see that?

A. Yes, sir.

Q. What is Bluenull LLC?

A. It's a small consulting group I put together more than maybe

15 years ago. And the basic idea is we provide statistical consultations to folks like this case or pharmaceutical industry and government university, anything related to quantitative science, we provide service.

Q. Now, for that consulting group, would you agree that the pharmaceutical industry is your top client?

A. Well, we actually had a few projects with pharmaceutical industries.

Q. Right. Bluenull LLC has received more money from pharmaceutical industry than any other sector, correct?

A. For example, sir, as you started out -- what is other sectors?

Q. Government, university?

A. Of course. Of course. We don't do much for university professors.

Q. Okay. And so my question is, you would agree that the pharmaceutical industry is your top -- sorry. Strike that question.

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You would agree that Bluenull LLC has received more money from pharmaceutical industry than any other sector, correct?
A. Well, not quite. Depend on which year. One year we work as the plaintiff side for Toyota braking system, security issue. The Bluenull was in the plaintiffs side.
So we didn't work for Toyota, for example.
So it is not really -- sorry, sir. It's not only --
Q. It's all right.
A. -- for pharmaceutical area. Actually it's more than that. You know, like, on this case, right, legal case, in this sector.
Q. Yeah, my question isn't just one year. You said that you started this 15 years ago. So looking over the last 15 years, you would agree that Bluenull LLC has received more money from pharmaceutical industry than any other

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sector, correct?
A. Correct.
Q. Okay. Now, you just told me about one time that Bluenull LLC represented a plaintiff. And that was against Toyota; is that correct?
A. Correct.
Q. And when we say Bluenull LLC, were you the expert in that -- were you a disclosed expert in that Toyota case where you were representing the plaintiff?
A. I was only -- I think I was one of the consultant, because we have many, many consultant at -- to Bluenull. We probably roughly have ten professors from Harvard, from Stanford, Northwestern University. People actually around the country actually are members of a consulting group.
So I believe for the Toyota case, we actually had more than me involved in that case. That is usually the case. For example, Lipitor case for

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Pfizer, we had five -- five faculty members in the group working together for the case. So not only me.
Q. Were you personally involved in the Toyota case?
A. Yes, sir.
Q. Now, other than the Toyota case, were you -- did you ever represent any other plaintiff?
A. Yes. I remember a couple times we represent people accused by Medicare fraud. I believe we were on the plaintiff's side.
Q. Okay. So in a situation where people are accused of Medicare fraud, if you're on the plaintiff's side, which party would you have been representing?
A. We have -- represent a doctor, and he was accused by Medicare, and, say, overcharge patients or something like that.
Q. So you represented the doctor who is being accused of

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overcharging patients?
A. Which is an inappropriate accusation, in my opinion, but yes.
Q. I see. But in that situation, you would have actually been representing a defendant, correct? Because he was being accused. He was the accused. He was being accused of overcharging patients, so he would have been a defendant in that case, right?
A. Yes. Another case I cannot release to you right now is ongoing. It's from -- I also work for plaintiff, because the other side is actually accused.
I'm sorry. I get it confused. It's still defendant. The plaintiff's side is government.
Q. Okay.
A. The commission. But anyway, I'm sorry. I apologize for that.
Q. So that other case that you're thinking of, you actually represent the defendant in that case,

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right?
A. Yes. Yes.
Q. Okay. Other than the plaintiff that you represented in the Toyota case, is there any other plaintiff that you've represented in your career?
A. For my, it's not. But I'm not for sure for other consultants because I don't worry about other consultant in the group. Whether they did, I have no idea.
Q. Well, for right now, my questions -- take away Bluenull for now. I'm just asking about you.
Are you aware of representing, in your career, other than the plaintiff in the Toyota case, any other plaintiff?
A. No, not I can recall.
Q. Okay. Let's talk about the Toyota case. Tell me what your involvement was in the Toyota case.
A. Toyota case was very interesting. So many years ago, people

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bought a Toyota with electronic braking system, which was new, replacing so-called mechanical braking system.
Somehow when people step on the brake, and the car, instead of stopping, is accelerated. So that caused some personal injury, also economic loss.
Economic loss was the case plaintiff and -- submitted to the court. And we actually helping plaintiff's side to -- to actually -- against -- against the Toyota. That's the case.
Q. And when did you get first involved in that case?
A. When? Sir, I'm sorry?
Q. Approximately when did you first got involved in that case?
A. I don't remember now. But we can Google easily the case, you know, using Toyota, the braking system. It must pop up.
Q. Is it more than ten years ago that you first became involved in that case?

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A. I think it's less than ten years, but it's close.
Q. Close to ten years ago?
A. I cannot tell exactly.
Q. Okay. Yeah, I'm not asking for exactly. Do you believe it was close to ten years ago that you first became involved in that Toyota braking case?
A. Sir, I really want to double-check before I answer your question.
Q. Okay. And you said that you would search Google, you would see when they first brought those cases, but how would that tell you when you first became involved? Because I don't think if we search Google, it will say Dr. Wei became involved -- first became involved in the case at this time.
So how would you search Google to tell when you first became involved?
A. No, no, sir. What I'm saying, you ask me when was that case. I

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said in general we can Google to find out.
If you're asking me specifically when I was involved, I have to go back to check my e-mails, if I still have it, and I can get back to you on that issue. I thought you were asking me, when was the Toyota case, not asking me when I got involved in that case. Correct?
Q. Actually. I am asking you when did you first become involved in that Toyota case?
A. Then I cannot Google. You said -- I'm not a famous person yet. So I think -- but I can easily -- if I still keep the e-mails, I can probably tell you exactly when I was involved in Toyota case.
Q. Would you feel comfortable in saying it was between five to 10 years ago?
A. Sir, I don't know why you want me to tell you exactly the timing.

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Is that very important to you? If it's so important, I can use lunch break to figure out for you.
Q. I'm asking you for your memory. You know, I'm not asking for exact times. So do you have any -- any way of being able to describe about how long ago that you first became involved in that case?
A. Okay. That's fair question. I don't know why it is so important for this case.
Q. You know, let's do this. I would appreciate if you don't try to question why something is important. If I'm asking the question, I'm allowed to ask the question.
So let's go forward again on this again.
Do you have any way of being able to describe about how long ago that you first became involved in that case?
A. I don't remember, sir.
Q. Okay. So you wouldn't be

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able to say if it was five years ago, ten years ago, or 15 years ago, as you remember here?
A. No. Less than 15 years, that's for sure.
Q. Less than 15. Okay. All right. Back to the billing.
MR. NIGH: We can put that back up there.
BY MR. NIGH:
Q. Okay. We can see the date at the top again, if you don't mind.
Here we can see Bluenull, and then we can see the date, August 3rd, 2021. And then it says, "To: Greenberg Traurig," correct?
A. Yes.
Q. And it's your understanding that it was Greenberg Traurig who retained you for this case?
A. I'm sorry, sir. Say it again, please.
Q. Were you retained on behalf of Greenberg -- on behalf of Teva or by

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Greenberg Traurig?
A. Yes, sir.
Q. Okay. And taking a look down, we can see your hours. And it says that you spent a total of 45.65 hours on this project between July 9th and August 2nd.
Do you see that?
A. Yes, sir.
Q. Now, that would be, you know, over 45 hours in less than a month, correct?
A. Yes, sir.
Q. And you only first became involved July 9th after Dr. Madigan submitted his expert report on July 6th, correct?
A. I don't remember on July 9th I got exactly Dr. Madigan's report that day or not. But I remember I got a listing of references from the lawyers on July 9th asking me to review.
Q. Okay. So Dr. Madigan submitted his report at the beginning of

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July.
MR. NIGH: Actually, let's go back to Madigan's report. LP-1558.
Let's blow up the signature and the date.
BY MR. NIGH:
Q. Do you see that signature, and, right below it, it's signed July 7, 2021?
A. Yes, sir.
Q. So you only -- you only became involved a couple days after the date of this expert report, correct?
A. Correct.
Q. Okay. Let's go back to your billing. And when you first were involved, my understanding is on July 9th, you got a list of references from the defense attorneys, correct?
A. Correct.
Q. And then you also had a DropBox with those studies, correct?
A. I don't think on July 9th I

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got a listing from the DropBox yet.
Q. Okay. Do you know approximately when you got the DropBox of studies?
A. I'm not quite sure. Maybe a week afterward, like three or four days. I don't recall, sir.
Q. Okay. If we take a look at the bottom here, the next page. It shows August 2nd, .8 hours.
Do you see that?
A. Yes, sir.
Q. Now -- and that's the last date on this invoice.
Between August 3rd and today, how long -- how many more hours have you spent on this case?
A. I don't know exactly the number of hours, sir. I need to go back and check my e-mails. I haven't tabulated the number of hours that I've been working on this case after August 3rd.
Q. Okay. Do you see how each

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of these dates has a number of hours, 7/23, three hours; 7/24, 6 hours; 7/25, 2.5 hours?
Would you be writing down those hours simultaneously as doing the work each day?
A. No. What happens in my practice -- I don't know other consultants. At end of the day, I just -- every time I had a conference call, I roughly estimate how many minutes I been on the call that day.
Usually I write it up right away after the call and how many hours I reviewed the documents right after I'm recording how many hours, piece by piece. Then end of the day, I actually put up a number, add the total number of hours for that day.
Q. Okay. And so at the end of the day you would total up your number of hours for each day that you spent time on this case, correct?
A. Yes, sir.

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Q. Did you keep doing that after August 3rd?
A. I believe so, yes.
Q. So where do you keep that information, the number of hours that you spent each day?
A. I'm not very good at lawyers. I know my assigned lawyer, he has very good software to doing this kind of thing.
I usually just very casually put in an e-mail, and I put it -- e-mail, send it to myself, so I have a record. And then towards the end of the day, I just go through this and add it up.
Q. So that's what I'm asking for. I'm not asking for each individual, you know, e-mail. I'm asking for where do you tabulate at the end of the day, where do you keep those hours? You say at the end of the day you add them up. You put them somewhere. Where do you put those hours that you've added up at the end of each day?

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A. Basically, for example, I have three e-mails related to the case today. And end of the day, I look at three, the last e-mail, I just put it down the total number for that date, that's it.
Q. Oh, I see. So what you're doing is your last piece of work assignment or last e-mail that you received for the day, you will put your total number of hours in that e-mail?
A. Yes, sir.
Q. Okay. So you would need to go back through each of those e-mails to be able to get the total number of hours that you've completed since August 3rd, correct?
A. Yeah, very inefficient, but that's the way I did it for many years.
Q. Okay. What's your best estimate in terms of your total number of hours that you spent between August 3rd and today?
A. My best estimate, probably

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30 or 35 hours total. But I'm not quite sure. I haven't counted today's yet. I don't know how many hours that you're going to spend with me or even tomorrow.
Q. No, I understand. I'm talking about -- let's -- your best estimate before -- let's say between August 3rd and yesterday, is it still 30 to 35 hours?
A. Yeah. Sorry.
Yeah, I think it's between 30 and 35. That's my rough guess, sir. Again, I apologize, I don't know exactly the number.
Q. Okay. Do you believe the valsartan -- the NDMA in dietary studies or the NDMA is somehow different -- sorry. Strike that.
Do you believe the NDMA -- exogenous NDMA in foods is somehow different or acts differently than the NDMA in valsartan?
A. Sir, I am not a toxicologist. I cannot make that

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comment. I have no opinion on this.
Q. Okay. And you're not a pharmacologist either, so you haven't looked at anything in regards to pharmacokinetics, correct?
A. Correct.
Q. Okay.
MR. NIGH: Let's take a look at LP-1474.
(Document marked for identification as Exhibit Wei-6.)
MR. NIGH: This will be marked as Exhibit -- Wei Exhibit 6.
BY MR. NIGH:
Q. At the bottom, you can see World Health Organization, Geneva 2002.
And in the center you can see nitrosodimethylamine.
Do you see that?
A. Yes, sir.
Q. Do you know what nitrosodimethylamine stands for -- or

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what that is?
A. I thought that is the DM -- NDMA; is that correct?
Q. Yes. And so this is a report from the WHO in 2002 on NDMA.
Before today, have you ever seen this?
A. I did see it. I didn't read it word by word. And I did a glance over.
Q. Okay. So you have seen this before today?
A. Yes.
Q. And you said that you glanced over it?
A. Yes.
Q. Okay. Let's take a look at Page 4.
MR. NIGH: Let's blow up the paragraph on the right side, third paragraph down.
BY MR. NIGH:
Q. And here it says, "Based upon laboratory studies in which tumors

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have been induced in all species, examined at relatively low levels, NDMA is clearly carcinogenic."
Do you see that?
A. Yes, sir.
Q. Now, today, you're not offering any opinions as to whether or not NDMA is carcinogenic, correct?
A. No.
Q. Okay. And also you didn't review any of the laboratory studies in which tumors were being induced in species when administered NDMA, correct?
A. Correct.
Q. Okay. Here, next it says, "There is overwhelming evidence that NDMA is mutagenic and clastogenic."
Do you know what mutagenic and clastogenic refer to?
A. No, sir.
Q. Okay. At the bottom it shows, "Qualitatively, the metabolism of NDMA appears to be similar in humans and animals. As a result, it is considered

highly likely that NDMA is carcinogenic to humans, potentially at relatively low levels of exposure."

Do you see that?

A. Yes, sir.

Q. And you did not review human tissue studies where they were analyzing the metabolism of NDMA, correct?

A. Right.

Q. Taking a look at the next page, on the upper left corner.

It says, "Cancer is clearly the critical endpoint for quantification of exposure relationship for risk characterization of NDMA. In addition to it being best characterized, in general, tumors occur at lowest concentration compared with those typically reported to induce noncancer effects."

Do you see that?

A. Yes, sir.

Q. And you didn't perform any sort of risk assessment analysis in terms of looking at, you know, at what levels

or concentrations of NDMA tumors would be induced, either in animals or humans, correct?

A. No, sir. But that was not on my assignment.

Q. Okay. And then at the bottom it says, "NDMA is a genotoxic carcinogen and exposure should be reduced to the extent possible."

Do you see that?

A. Yes, sir.

Q. And you have no reason to disagree with the WHO when they say that NDMA is a genotoxic carcinogen and exposure should be reduced to the extent possible, correct?

A. Well, it depend on disagree, or agree. You asking me. I said this document is very old, almost 20 years old. I'm surprised they didn't even up-to-date this website or the report. I'm surprised this is 20 years old, the document is still existing.

Q. I'm sorry. You're surprised

they haven't updated this report since then?

A. You know it's 20 -- almost 20 years, right, sir.

Q. Have you seen updated reports from various --

A. No.

Q. -- agencies where they updated their analysis on NDMA?

A. I don't think they have updated, as far as I know.

Q. As far as you know, you are not aware of any other agencies, health agencies or regulatory agencies that have updated their opinions on NDMA and whether or not it's reasonably anticipated to be carcinogenic?

A. I don't think -- if there is one, I would be happy to read it, sir.

MR. NIGH: Let's take a look at 23.

BY MR. NIGH:

Q. Now, other than the update, the question on whether or not it's been

updated in 20 years, do you have any other reasons to disagree?

A. Well, I'm not a -- I'm sorry, sir. I don't mean to talk over you. I'm sorry. Why don't you finish.

Q. No, that's okay. Do you have any other reasons to disagree with the WHO?

A. No, sir. I don't know this WHO's position, you call this document, or paper, whatever you want, right. But I'm saying in general, any animal study trying transported to human study, and we know very well, sometimes just doesn't work. It's trivial.

And that's why we need human studies to confirm what the WHO, the position papers, right. But I'm surprised, so many papers published afterwards, WHO did not have updated version. That's my understanding, right. If you have updated version, I'd be happy to read it.

Q. But my understanding is that

you haven't reviewed any updated position papers from any of the agencies that have, you know, discussed NDMA and it being a probable carcinogen and/or reasonably anticipated to be a human carcinogen, correct?

A. Yeah, from human being -- from human being studies.

Q. Okay. Let's take a look at -- now, if there were other regulatory agencies that have looked at updated epidemiological studies and included that in their assessment, isn't that something that you would want to review?

A. Oh, yeah, for sure. I'd love to read it.

MR. NIGH: Okay. Let's take a look at 23 on the right side. First paragraph.

BY MR. NIGH:

Q. And here they say, WHO says, "Therefore, owing to the considerable evidence of carcinogenicity of NDMA in laboratory species, evidence of direct

interaction with DNA consistent with tumor formation, and the apparent lack of qualitative species-specific differences in the metabolism of this substance, NDMA is highly likely to be carcinogenic to humans."

Do you see that?

A. Yes, sir.

Q. Now, I just want to confirm, you didn't look at any studies on NDMA in laboratory species, correct?

A. Correct.

Q. You didn't look at any studies on the evidence of direct interaction with DNA consistent with tumor formation, correct?

A. Correct.

Q. And you didn't look at any studies that showed whether or not there was an apparent lack of qualitative species-specific differences in the metabolism of NDMA, correct?

A. Correct.

MR. NIGH: Okay. We can put

this away.

BY MR. NIGH:

Q. We've been going over a little over an hour. Would you like to take a break about now?

A. No. If you want to take a break, you know, go ahead. But I'm okay.

Q. Okay. Let's keep going.

All right. We'll take a look at LP-1577. This is your report again.

Now, Doctor, during Dr. Panigrahy's deposition, defense counsel asked Dr. Panigrahy multiple questions regarding a couple of sentences that he had that were identical between his Actos report and his valsartan report, a couple sentences out of a 256 -- 250-plus-page report that he submitted in valsartan.

Did you review that testimony at all?

A. No, I don't.

Q. Now, would you be worried

yourself about a criticism like that, that there are identical sentences from one past expert report versus a -- the report that you produced here today?

MR. MERRELL: Objection to form.

THE WITNESS: I'm not quite sure of your question. You said am I worried about it? I didn't have access to other experts' reports? Is that what your question?

BY MR. NIGH:

Q. Would you personal --

A. I don't understand your --

Q. Would you be personally worried if there was a problem with cutting and pasting or having identical sentences from a past expert report and the expert report you've submitted in valsartan?

MR. MERRELL: Objection to form.

THE WITNESS: I'm not quite

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sure which part you're talking about. For example, for my quantification, usually I usually use older things. I use it many, many times for legal case, almost identical, except for up-to-dated the number of publications or new award I received.

I just simply up-to-date it. If you said, well, you know, you shouldn't cut and paste from previous report. I say, well, it's my report. I can do anything that I wanted to, right. I can copy every word I wanted to, as long as it reflect the truth.

BY MR. NIGH:

Q. So it's your belief that -- you know, not just qualifications, but if you had it in a prior report, that you could do anything you wanted with that prior report and cut and paste or copy any word that you wanted from a prior report into this report, as long as it

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reflects the truth, correct?

A. Well, you say any word. That's a very strong word, sir. I just -- we can repeat many, many word, right. I mean, I don't mean to play the word game here with you, sir. I'm just wondering what is wrong with me citing the principle of statistical methods, right? That's the same old thing, right? Why should I every time write a legal expert witness report, I have to redo it changing the wording with the time, because the principle is there.

The same wording, we can use repeatedly. Then for this case, what's new? Then I'm going to add in my new opinions, right? I don't see anything wrong with that, sir.

Q. So it's your testimony that if it's the same principle that's being repeated from a past report into this new report, that you don't have any problem with it having the exact words, as long as it's the same principle that's being

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applied for both reports, correct?

A. Correct.

Q. Fair enough. Okay.

MR. NIGH: Let's take a look at -- let's take a look at LP-1562.

(Document marked for identification as Exhibit Wei-7.)

MR. NIGH: Let's go ahead and blow up the In Re Bextra and Celebrex Marketing.

BY MR. NIGH:

Q. Do you see this, Doctor?

A. Yes.

Q. It says expert report of Professor -- and it's you, right, Dr. Wei?

A. Yes, sir.

Q. Okay. And here it says, "Name of expert, Dr. Wei." And it says, "Representing the defendant."

Is that accurate, that in the Celebrex case, you were representing

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the pharmaceutical industry defendant?

A. Yes, sir.

Q. Okay. And let's take a look below.

MR. NIGH: If we can blow up the table of contents.

BY MR. NIGH:

Q. Here, you had a table of contents for this report.

Do you see that?

A. Yes, sir.

Q. And then we can take a look at the next page.

MR. NIGH: Let's blow up the table of contents there as well.

BY MR. NIGH:

Q. And that continues with the table of contents that you have with this report.

Do you see that?

A. Yeah.

Q. And then let's look at introduction.

And it says, "1. I received

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a Ph.D. degree in statistics in 1975 from the University of Wisconsin. I have been a tenured professor of biostatistics at Harvard University since 1991 and a professor of biostatistical science and computational biology at Dana Farber Cancer Institute, Harvard Medical School, since 1997."

Do you see that?

A. Yes, sir.

Q. This is describing you, correct?

A. Sorry, sir. Say again.

Q. I said this is -- these qualifications are describing you, correct?

A. Yes, sir.

Q. Okay. And looking at assignment, Number 4. Assignment, it says, "I have been asked to determine whether Celebrex, at a daily dose of 200 milligrams, 400 milligrams, and 800 milligrams is associated with the specific risk of cardiovascular events

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relative to placebo and non-selective nonsteroidal antiinflammatory drugs based on reliable datasets accessible to me from comparative clinical trials."

Do you see that?

A. Yes, sir.

Q. And so in the Celebrex case you had clinical trials that you were analyzing, correct?

A. Yes, sir.

Q. Are you aware of any clinical trials in this case that have compared people contaminated with NDMA, valsartan -- or people taking contaminated NDMA valsartan compared to people taking uncontaminated valsartan?

A. No, sir.

Q. There aren't any such clinical trials that would be of relevance in terms of your opinion for this question that you've looked at in valsartan, correct?

A. I don't have it actually. The only thing that I'm worried about

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is -- or concerned about is Dr. Madigan's references.

Q. Right. And so in the valsartan -- in the valsartan case, you actually haven't looked at any data regarding clinical trials, correct?

A. No, sir.

Q. Let's put that one to the side. We'll come back to it later.

MR. NIGH: Let's take a look at LP-1561.

(Document marked for identification as Exhibit Wei-8.)

MR. NIGH: This will be marked as Wei Exhibit 8.

BY MR. NIGH:

Q. Here you see it says, "In Re Taxotere Products Liability Litigation."

The date shows February 8, 2019.

Do you see that?

A. Yes, sir.

Q. Do you recall just giving

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your Taxotere expert report a little over two years ago?

A. I vaguely remember, but not very detailed anymore.

Q. Okay. And here it says, "Expert report of Dr. Wei," correct?

A. Yes, sir.

Q. Okay. And again, you were representing the defendant pharmaceutical company in this case, correct?

A. Correct.

Q. And in the introduction -- if you see the introduction, which is the first couple sentences, it says, "I received a Ph.D. in statistics from the University of Wisconsin. I have been a tenured professor of biostatistics at Harvard University since 1991 and was a professor of biostatistical science and computational biology at Dana Farber Cancer Institute, Harvard Medical School, between 1997 and 2012."

Correct?

A. Yes, sir.

Q. So this again, this is describing you, correct?
A. Yes, sir.
MR. NIGH: Let's take a look at LP-1579.
(Document marked for identification as Exhibit Wei-9.)
MR. NIGH: This is being marked as Exhibit 9.
BY MR. NIGH:
Q. Here it says, "Bone Care International LLC and Genzyme Corporation."
Do you see that?
A. Yes, sir.
Q. And here it says, Doctor -- it's an expert report on October 30, 2009, correct?
A. Yes, sir.
Q. And Bone Care International LLC, that's another -- that's a corporation. The plaintiff here is a corporation, correct?

A. Sorry, back in 2009, my memory is really fuzzy about this case. So if you can remind me of what's going on, I would really appreciate it.
Q. Okay. Let's take a look at the -- let's take a look under summary of opinion.
It says, "I have been asked by counsel for Genzyme to investigate whether there is a difference in treatment of secondary hyperthyroidism in" -- "hyperparathyroidism in patients with end stage renal disease using either" -- I'm not sure I can pronounce that. -- "doxercalciferol administered intravenously or calcitriol administered intravenously with respect to side effects using data from two studies that were reported."and then it gives those cites.
Do you see that?
A. Yes, sir.
Q. Does that help refresh your recollection?

A. No, not really. It has been too long.
Q. Do you know that in this case you were representing a corporation?
A. Say it again, sir.
Q. Do you know that in this case you were representing a corporation?
A. I'm not quite sure I understand your question. I mean, I'm representing Genzyme here, right.
Q. Genzyme.
A. Right.
Q. Do you know that Genzyme is a corporation?
A. Yeah, it used to be by itself, an independent drug company. They bought by Sanofi, I think.
Q. I see. So Genzyme is a pharmaceutical industry corporation, correct?
A. Yes, sir.
Q. Got it. So this is another case where you're representing pharmaceutical industry, correct?

A. Well, sir, if I remember, the plaintiff was also a corporation.
Q. Right.
A. It's not like -- it is fair game.
Q. It's pharmaceutical company against pharmaceutical company, and you were representing one of the pharmaceutical companies, correct?
A. Yes, sir.
MR. NIGH: Okay. Let's go up on this expert report at the top of the page, and it says -- where -- three and four, let's highlight that all the way down to summary of opinions, yes.
BY MR. NIGH:
Q. Here it says, my CV -- I'm not going to go into that.
Number 4, it says, "My previous deposition and trial experience is as follows."
And it shows Western Division Cincinnati Services.

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Do you see that?
A. Yes.
Q. And you represented the defendant in that case, correct? Do you see where it says defendant?
A. Sorry, yeah. I -- for the defendant, yes, sir.
Q. And next is Ortho Biotech Products versus Amgen.
Do you see that?
A. Yes, sir.
Q. And you represented the plaintiff, but here the plaintiff is a pharmaceutical industry, correct?
A. Yeah. This is a corporation against a corporation, yes.
Q. Pharmacy industry against pharmacy industry again, correct?
A. Correct.
Q. And next it says, Bracco Diagnostics versus Amersham Health Incorporated.
Do you see that?
A. Correct.

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Q. And here it says for defendant and plaintiff. Did you represent both the defendants and the plaintiffs in this case?
A. Well, this is interesting case. Actually, they're suing each other.
So in one case -- it's the same company.
Q. Right. But this is another -- this is another one of, you know, pharmaceutical industry against pharmaceutical industry, correct?
A. Correct.
Q. Okay. And so you would have represented pharmaceutical industry in that case, correct?
A. Against another one, yes.
Q. And then next we have Howmedica Osteonics versus Zimmer.
Do you see that?
A. Yes.
Q. And you represented Zimmer here, correct?

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A. I apologize. I don't remember now. This is 2007.
Q. It says, for defendant.
Do you see that?
A. Yeah, I mean, again, if it's against Zimmer, then I'm for the defendant, yes.
Q. But nonetheless, here again, I know we keep saying pharmaceutical. But medical device and pharmaceutical company. This is another one of those where we see pharmaceutical/medical device company against pharmaceutical/medical device company, correct?
A. Correct.
Q. Okay. And so you've represented again a pharmaceutical company/medical device company, correct?
A. Correct.
Q. And then we saw Bextra and Celebrex. And you represented a pharmaceutical company in that case, correct?

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A. Yes, sir.
Q. And then In Re Pfizer, is the next one, securities litigation. And you represented the pharmaceutical company in that case as well, correct?
A. Yes, sir.
Q. Okay. Is it fair to say that the vast majority of your expert opinions are on behalf of pharmaceutical companies?
A. Yeah, as you can see, against another company, not really against an individual cases.
Q. Right. But my question is not necessarily who they are against. But the vast majority of your representation would be on behalf of pharmaceutical companies or medical device companies, correct?
A. Yeah, for some -- you know, I'm really impressed, sir, you dig out of the interesting case that I was working.
The second -- the first one, Western Division Cincinnati Women, that

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was a really interesting abortion case. And I was not concerning about any company or anything. It's actually we fight for women's right.

The other side -- you know, that's a very interesting case, actually.

Q. Well, interesting that you brought that up. But you about you were actually on the side of the defendant, where you were looking to uphold a law that actually made it more difficult for women to be able to have abortions after a certain time frame, correct?

A. Correct, yes.

Q. Okay. So you weren't actually in that case fighting on behalf of women's rights. You were actually on the other side, right?

A. Yeah, you're right.

Q. Okay. Other than that case, wouldn't you agree with me that the vast majority of your opinions are on behalf of pharmaceutical companies or on behalf of medical device companies?

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A. Yes, sir.

MR. NIGH: Okay. Let's go ahead and take a look at LP-1577. We'll mark this as Wei Exhibit 10.

(Document marked for identification as Exhibit Wei-10.)

BY MR. NIGH:

Q. Here you can see it's called A Woman's Choice East Side Women's Clinic versus Scott Newman.

Do you see that? It says, et cetera, et al., defendants?

A. Yep.

Q. And this is the case that we were just talking about, right?

A. Yeah.

Q. Okay. And this is the case where you were on the side of trying to uphold the law that made it more difficult for women to get abortions, correct?

A. Sir, I'm not so for sure that I would use your word "more

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difficult" for women seeking abortion. I think that's not appropriate word.

We are asking the court upheld the law established by the state of Indiana, Ohio, was --

Q. Well, this is a law. Sorry. I didn't mean to interrupt you. Go ahead.

A. So if I remember, sir, this is a 1999, right?

Q. Yeah.

A. That was a long, long time ago. And if I remember correctly, the Indiana, example, state, had some kind of abortion rules, right. For example, in Mississippi, I believe it's like 24 hours or 48 hours waiting period. Forgive me, sir. I don't remember detail anymore.

Basically, just saying, look, if a woman looking for abortion after first contact with the clinic, and she should wait about a time -- I don't know one day or two days. Then go backwards.

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Some people were just wondering, maybe they can settle down and reconsider the situation after they got the information from the clinic and they can actually make a better decision instead of, like, walking into the clinic, like I go to fast food store or like a McDonalds, right?

If I want to have abortion, then I'm going to do right away. So that's basically the principle, should we have this waiting period.

And the state legislature established and say could you please keep this rule.

That's what my understanding, my memory, my recollection.

Q. Do you recall stating in here that you would agree with a law that says banning abortions after 15 weeks of pregnancy that you would support that?

A. I don't remember exactly the weeks of the pregnancy anymore, sir.

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This has been long time.
Q. Okay.
MR. NIGH: Let's move on from that. Let's go ahead and take a break at this point.
THE VIDEOGRAPHER: The time right now is 10:34 a.m. We're off the record.
(Short break.)
THE VIDEOGRAPHER: The time right now is 10:54 a.m. We're back on the record.
BY MR. NIGH:
Q. Now, doctor, remember we were talking about cutting and pasting from prior reports. And you said that it wouldn't be uncommon for you to cut and paste information from your qualifications into your reports, correct?
A. Sorry, Counsel, your picture is so fuzzy.
Okay. What I was saying, sir, is this, like, my job description, I

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think it's perfectly all right to just use the same old language, right. Nothing wrong with that.
If I stated the principle, the principle of a statistical method, that never changes so far, it is all right.
But if you're actually dealing with a new case, if a new situation, then I don't think we just repeat what we said before, right, which may not be relevant.
Q. I'm not going to look at your qualifications for now in terms of comparing your results. I'm going to look at your analysis. Okay. We're going to skip past qualifications.
I think you would agree with me that you would commonly take the same information in your qualifications in one report and put it into other reports, correct?
A. Correct. Sorry, Counsel. Could you show your picture again? Could

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talk again. I think I want to click again. It's very fuzzy somehow.
MR. MERRELL: It's fuzzy for me too.
MR. NIGH: Okay. Let's go ahead and get off the record and see if we can fix the fuzziness.
THE VIDEOGRAPHER: The time right now is 10:56 a.m. We're off the record.
(Brief pause.)
THE VIDEOGRAPHER: The time right now is 10:58 a.m. We're back on the record.
BY MR. NIGH:
Q. Okay. I think you would agree with me that you would commonly take the same information in your qualifications in one report and put it into other expert reports, correct?
A. Correct.
Q. Okay. Let's -- what I want to do is get past that and look at your analyses between -- and compare it

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between these reports.
MR. NIGH: So let's go ahead and, side by side, I want to have LP-1557 and LP-1561.
BY MR. NIGH:
Q. Side by side, we're going to look at your expert report that you provided here in valsartan with your expert report that you provided in Taxotere. Okay.
MR. NIGH: Let's take a look at Page 7 of the valsartan report. Valsartan, go to Page 7. Yes. And then on Taxotere we will go to Page 2.
Let's blow up this first paragraph for valsartan that starts with "Suppose." Let's blow that up.
And then let's blow up on the other side Paragraph 12 that starts with "Suppose."
And let's -- can we make that just a tad bit, I'm not sure

if it's to make that other "suppose" bigger.

BY MR. NIGH:

Q. What we see, on the left side is your expert report, valsartan. It starts off with, "Suppose that we are interested in the rate of occurrence of a certain clinical event, for example, cancer, among subjects exposed to NDMA or NDEA and their counterparts are control."

On the Taxotere side, it says, "Suppose that we are interested in the rate of occurrence of a certain clinical event, for example, permanent alopecia among patients treated with Taxotere relative to its counterpart, control, for patients who have been exposed to other treatments."

Do you see that?

A. Yes, sir.

Q. Now, you would agree that the structure of those sentences are very similar, and essentially what it appears you have done is take out what was

relevant to Taxotere and plug in what's relevant for valsartan, correct?

A. Well, that's -- I change the word here, right. Not exactly copied the same old thing like on the left -- right-hand side.

Q. Right. At the time that you're doing your valsartan report, you had your Taxotere report. And you used the Taxotere report as your framework for the valsartan report, correct?

A. For statistical principles here.

Q. Right. But you used your Taxotere report as your framework for your valsartan report, correct?

A. I used the same -- similar format to describe statistical methodologies from Taxotere case to the valsartan case.

Q. Okay. And in fact, you used a lot of similar word structure throughout the report in Taxotere compared to your report in valsartan,

correct?

A. For statistical principle, yes.

Q. Well, let's look at the next line. It says -- in the next line, it says, "In the first step" -- on the valsartan side. "In the first step, and we take a sample from a population of subjects exposed and another example from the population of subjects who were not exposed."

On the Taxotere side, "In the first step, we take a sample of the population of patients treated with Taxotere and another example from the population of patients who did not receive Taxotere."

You would agree those sentences are very similar, correct?

A. Correct.

Q. On the left -- on the left side, your valsartan report, you say, "Assuming that these samples are valid representatives of the two populations,

quantitative analytic methods can be used to determine whether the exposed group has higher, lower, or similar event rate than that for the control group."

On the other side, you say, "Assuming" -- on Taxotere, you say, "Assuming that the samples are valid representatives of two populations, quantitative analytic methods can be used to determine whether the Taxotere group has a higher, lower, or similar rate" -- "event rate than that for the non-Taxotere group."

Do you see that?

A. Yes, sir.

Q. You would agree those sentences are very similar, correct?

A. Yes, sir.

Q. Next, on the valsartan side, it says, "Since we draw conclusions based on a subset of subjects, any qualitative or quantitative interpretation of the result, whether the rate is higher or not, is subject to sampling error."

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On the Taxotere side, you say, "Since we draw conclusions based on a subset of patients, any qualitative or quantitative interpretation of the result, whether the rate is higher or not is subject to sampling error."

Correct?

A. Yep.

Q. Those are sentences that appear in both these reports, correct?

A. Correct.

Q. On the valsartan side, you say, "That is, the observed event rate may be higher leading to a possible false positive finding."

MR. NIGH: And we can go down to the next -- yep, very good. There.

BY MR. NIGH:

Q. "That is, the observed event rate may be higher, leading to a possible false positive, or lower leading to a possible false negative finding, than the true event rate in the population."

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On the other side you have, "That is" -- for Taxotere, you have, "That is, the observed event rate may be higher, leading to a possible false positive finding or lower leading to a possible false negative finding than the event rate in the population."

Those are the exact sentences, correct, in both reports?

A. Yes, sir.

Q. Next, going down on the valsartan side, on Page 8, it shows, "An efficient statistical method for analyzing such data minimizes the chance of making these two types of errors."

And then on the Taxotere side, it says, "An efficient statistical method for analyzing such data minimizes the chance of making these two types of errors."

Those are exact sentences in each of those reports, correct? Correct?

A. Yes, sir.

Q. On the left side it says,

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"It is important to note that except for the exposure to NDMA or NDEA, the exposed subjects in the sample should be similar to the subjects in the non-exposed sample with respect to important observable or unobservable confounders."

On the right side you say, "It is important to note that except for treatment with Taxotere, Taxotere users in the sample ideally should be similar to patients in the non-Taxotere sample with respect to important observable or unobservable confounders." And then you list, "E.g., age, disease status, et al."

Do you see that?

A. Yes, sir.

Q. Those sentence -- that part of the sentence is very, very similar in both of the reports, correct?

A. Well, I missed example age and disease status.

Q. Right. You didn't list any examples in valsartan. You just listed them in Taxotere, correct?

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A. Yeah. Well, it's not identical. But I missed that part.

Q. Okay. Let's take a look at 18 on valsartan. And let's scroll down to the next paragraph.

So you followed that principle in your report in Taxotere with the same principle that you followed in your report with valsartan, Number 18 and 13.

It says, "After we have determined how to draw a valid sample size from the population of interest, one has to determine what clinical endpoints are most appropriate to quantify the exposure effect."

On the other side, "After we have determined how to draw a valid sample from the patient population of interest, one has to determine what clinical endpoints are most appropriate to quantify the side effect of the treatment."

Do you see that?

A. Yes, sir.
Q. Those are very similar sentences, correct?
A. Yes, sir.
Q. Next you have, "For the present legal case," on the other side -- in valsartan, you have, "For the present legal case."
And on the other side, you have, "For the present legal case."
Do you see that?
A. Yeah.
Q. And then on the valsartan side, you say, "For the present legal case, the endpoint is whether the subject had a certain type of cancer or the time to occurrence of cancer."
On the Taxotere side, you say, "For the present case, the endpoint is whether the patient had permanent alopecia or not."
Do you see that?
A. Yes, sir.
Q. So you basically plugged in

what's relevant for valsartan on one report and what's relevant for Taxotere on the other report, correct?
A. I used the same language.
Q. Same framework, correct?
A. Yes, sir.
Q. On the valsartan side, you say, "Suppose that, based on the sample of 100 patients, at the end of the study, four patients experienced such events."
On the other side, you used the same "suppose" identically.
"Suppose that based on a sample of 100 patients at the end of the study, four patients experienced such events."
Correct? Those are identical sentences, right?
A. Yes, sir.
Q. Next you say, "Obvious estimate of the event rate for the underlying population is .04 or 4 percent."
On the Taxotere side, you

say, "An obvious estimate of the event rate for the underlying population is .04 or 4 percent."
Those are exact sentences in each report, correct?
A. Correct.
Q. Next sentence, "This is called a point estimate."
On the Taxotere side, you have, "This is called a point estimate."
Those are exact sentences, correct?
A. Yep.
Q. Next you have, "However, this estimate is based on a sample of patients."
On the other -- Taxotere side, you have, "However this estimate is based on a sample of patients?"
Those are exact sentences in your Taxotere report and your valsartan report, correct?
A. Yep.
Q. On the valsartan side, you

have, "The true event rate for the entire population may be more or less than 4 percent."
On the Taxotere side, "The true event rate for the entire population may be more or less than 4 percent."
Those are exact sentences, correct?
A. Yeah.
Q. On the valsartan side, you have, "Different studies generating different samples may find a different proportion of subjects with cancer."
On the Taxotere side, you have, "A different study based on different sample may find different proportion of patients that experienced alopecia events."
Very similar sentence, correct?
A. Yep.
Q. Next sentence, you have, "Therefore" --
MR. NIGH: And we're going

to move onto Page 9 of the valsartan report.

BY MR. NIGH:

Q. "Therefore, when observing results of a single sample, it is important to attach a level of confidence to the observed point estimate."

On the Taxotere report, "Therefore, when observing results from a single sample, it is important to attach a level of confidence to the observed point estimate."

Those are exact sentences, correct?

A. Yep.

Q. On the valsartan side, "This quantitative scientific process is called drawing or making inferences about the true event rate."

On the Taxotere side, "This quantitative scientific process is called drawing or making inferences about the true event rate.

Those are exact sentences,

correct?

A. Yep.

MR. NIGH: Let's take a look at Paragraph 19. Let's compare to this Paragraph 21 in Taxotere.

BY MR. NIGH:

Q. Next you have, "Let me turn to the issues of comparing two groups of subjects, one having been exposed and the other being in the control."

And on the Taxotere side, "Let me turn to the issues of comparing two groups of patients, one receiving Taxotere and the other receiving a control."

Very similar sentences, correct?

A. Yep.

Q. On the valsartan side, "To make sure that two samples of subjects are comparable with respect to all potential confounders, we often rely on a randomized clinical trial setting."

On the Taxotere side, "To

make sure that two samples of patients are comparable with respect to all potential confounders, we often rely on a randomized clinical trial setting."

Do you see that?

A. Yep.

Q. Those are identical sentences, correct?

A. Yep.

Q. And here, in valsartan, you never looked at any clinical trials, whereas you looked at clinical trials in Taxotere, correct?

A. I just gave the information. The gold standard to investigate any difference between the two groups would be based on the clinical trial. That's the point.

Q. Right. But to try to set up a clinical trial where you expose patients to contaminated -- NDMA-contaminated valsartan, compared to patients who are unexposed to -- or not exposed to contaminated valsartan, but

given uncontaminated valsartan, to set up a trial setting where you were to give patients contaminated with valsartan as the test group, especially contaminated with levels 200 times over the threshold level set by the FDA, that sort of test would not get approval from any IRB that you know of, correct?

A. Well, sir, I think this paragraph is not really ask us to have clinical trials on valsartan case. I just wanted to presenting what is the gold standard, if we can do it.

The gold standard is using a clinical trial randomized. If we cannot do it, then we go to the next level of investigation.

I just want to point out why the randomized clinical trial gives us a gold -- so-called gold standard.

Q. I understand. My question is -- I'm sorry. Did I interrupt you?

A. No. No, sir.

Q. Okay.

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A. I'm just trying to explain what your question.
You asking me, can we do clinical trials for valsartan case?
I think this is -- in my humble opinion, we cannot do that, right.
I want to pointed out in Paragraph 19 here, I simply indicate to the judge, or to the court, I said, listen, what is the gold standard if we can do it, which is the randomized clinical trial, right.
Q. Well, as --
A. But -- sorry, go ahead.
Q. Sorry. I didn't mean to interrupt you.
As it relates to valsartan, clinical trials would not be a gold standard because it would be unethical to give -- to try to setup a clinical trial that tests whether or not people who are getting contaminated valsartan over a long period of time would get cancer or have an increased risk of cancer compared

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to control group, because you can't -- you wouldn't get -- you wouldn't be able to get approval for that sort of clinical trial, right?
A. Right. I don't mean that I said we needed to do it for randomized trials for valsartan case. Just in general, the gold standard is to conduct -- is to conduct a randomized clinical trial. If we cannot do it, then what is the best next level? That's what I'm trying to say.
Q. I understand. As it applies to valsartan, though, the gold standard would not be randomized clinical trials, because it would be unethical to conduct such a trial where you're giving people -- you're intentionally giving people NDMA-contaminated valsartan, correct?
A. Sir, in that case, what is the gold standard to evaluate valsartan case then? I have no idea what your definition by gold standard.

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There is no gold standard. If you cannot do randomized trial, there's no gold standard anymore.
Q. If you can't do a randomized controlled clinical trial, what would be the next best quality of evidence?
A. In my --
Q. If --
A. Go ahead.
Q. Sorry.
I added, if you can't -- let me repeat my question.
If you can't do a randomized clinical trial, what would be the next best quality of evidence in the hierarchy of scientific evidence?
A. For this case?
Q. For any case, if you're -- if it's unethical to conduct a randomized clinical trial, what would be the next best quality of evidence in the hierarchy of scientific evidence? It would be epidemiological studies, correct?
A. Well, I'm not an

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epidemiologist. I cannot speak for epidemiology. I'm just speak as a statistician. If you're asking me an epidemiology question, I cannot answer, sir.
Q. Okay. So as a statistician, you've given this statement that clinical trials are the gold standard.
You use that same statement in Taxotere where you're looking at randomized clinical trials. And then you also plug it into valsartan where it's unethical to do clinical trials. So if you can't use clinical trials, do you know the scientific -- hierarchy of scientific evidence would then next state that epidemiological studies would be the next best evidence?
A. I would say observational study instead of, quote, epidemiological studies if that's okay with you?
Q. That's okay. Observational studies correct?
A. Yeah. Yeah. That's what I

would say, observational studies.
Q. Now, observational studies are oftentimes commonly referred to as epidemiological studies, correct?
A. I don't know. If you're using your terminology, it's okay. If you think it's equivalent, that's in your book, I'm saying I prefer to use observational study. Is that okay with you?
Q. Yes. All right. Let's take a look at the next sentence. 19, if you can see, "Such a clinical study" -- this is for the valsartan -- your valsartan report.
"Such a clinical study yields a well designed experiment that has the potential for generating reliable prospective data on safety."
In your Taxotere report, "Such a clinical study yields a well designed experiment that has the potential for generating reliable prospective data on drug efficacy or

safety."
Those are exact sentences, correct?
A. Yes, sir.
Q. Next you say, such studies are conducted and monitored according to a pre-specified protocol which details the exposure administered (example, form, dosage, frequency), the clinical and biological endpoint (example, lab value, patient's quality of life, time to remission, time to a toxicity event), the study patient population and other clinical and statistical considerations."
In the Taxotere report, you put, "Such studies are conducted and monitored according to pre-specified protocol, which details the treatments administered (example, form, dosage frequency), the clinical or biological endpoints (example, lab value, patient's quality of life, time to remission, time to a toxicity event), the study patient population, and other clinical and

statistical considerations."
Those are exact sentences in your two reports, correct?
A. Yes, sir.
Q. Next, in valsartan, you put, "The trial is usually randomized and blinded."
On the other side, you put, "The trial is usually randomized, which means patients are assigned randomly to one of the study arms."
Very similar start of each of those sentences, correct?
A. Looks like different to me. But it's okay if you say similar.
Q. Well, your next sentence actually has the second half of the sentence from Taxotere. You put, "Such subjects are assigned randomly to one of the study arms."
That's very similar to the end of your Taxotere sentence, correct?
A. Yes, sir.
MR. NIGH: Then let's go down

to the "this avoids."
BY MR. NIGH:
Q. You put, "This avoids selection bias or other experimental bias."
On the Taxotere, "This avoids selection bias or other experimental bias."
Those are exact sentences, correct?
A. Yes, sir.
Q. Your next sentence in valsartan, "When appropriately designed, results from a well conducted randomized clinical trial are regarded as a gold standard in controlled settings to evaluate the efficacy and safety of an exposure."
On the Taxotere side, "When appropriately designed, results from a well conducted randomized clinical trial are regarded as a gold standard in controlled settings to evaluate the efficacy and safety of treatment."

Those are almost identical, correct?

A. Yes, sir.

MR. NIGH: Now, let's turn to, in your valsartan report, Page 19. Let's look at Paragraph 18 of Taxotere. And let's look at page -- Paragraph 18 of Taxotere and Paragraph 31 in valsartan.

BY MR. NIGH:

Q. At 31 you say, "Even if we accept Dr. Madigan's criteria with a false positive of .05 as an arbitrary threshold value."

And then I want to direct your attention to, "This procedure was generally used to establish the so-called statistical significance of a result when testing a single clinical endpoint in a single study."

Do you see that?

A. Yes, sir.

Q. Then in 18 you put, on the second part of that, after the comma, "Is

typically used by a study investigators and statisticians to establish the statistical significance of a report when testing a single clinical endpoint in a single study."

Do you see that?

A. Yes, sir.

Q. Do you see how both of those sentences are similar?

A. That's the basic principle, sir. This is a statistical principle.

Q. Next, let's have -- sorry. Go ahead.

A. This is a basic, like, a textbook language.

Q. On 31, the second sentence. "This level can be very liberal, i.e., can result in statements of statistical significance when none exist, if multiple statistical tests and/or studies are examined simultaneously."

On the right side, "The 5 percent level of significance for hypothesis testing can be too liberal,

can result in statements of statistical significance where none exist if multiple endpoints and/or studies are examined simultaneously."

Do you see how those sentences are almost identical?

A. Yes, sir.

Q. And this is in response to criticizing Dr. Madigan in looking at multiplicity, correct?

A. You know, sir, this is very interesting, because Dr. Madigan was the other side for the Taxotere.

He actually utilized the same methodology, observational study, in Taxotere.

So those two legal cases, Dr. Madigan's reports, yeah, very similar. So we have the similar concerns, right. That's basically -- he is violating the fundamental statistical principles to do his analysis.

Q. Let me see if I have this right, because I think what you're saying

is his reports look almost identical.

But have you looked at the report in Taxotere and looked at his report in valsartan? Have you seen that they're actually very different?

A. No, sir. I'm trying to say he used the same statistical principle to analyze both legal cases.

And both have had the same problem, a basic fundamental problem, against the statistical principles.

So I use the same language. I say, well, in the Taxotere, we already raised the issue. And you didn't answer very well. Why do you want to use the same flawed argument in a new case?

Q. Well, it's actually that you commonly criticize experts for not using or looking at multiplicity.

This is a common theme across your expert reports. It's not just for Dr. Madigan. We're going to look at Celebrex and we're going to look at several others. You commonly raise

the issue of multiplicity, because any time someone is looking at results from single studies, you want to make it a multiplicity issue, correct?

MR. MERRELL: Objection to form.

THE WITNESS: It's not for me, sir. If you check FDA's principle of drug approval process, they don't allow you to use a single study or multiple endpoint, right, without a multiple adjustment. Right. Everyone knows.

And in New England Journal of Medicine recently, saying you cannot reporting so many different P-values, if different endpoint anymore. You know, you can see the latest articles published in New England Journal of Medicine, they don't report P-value repeatedly for primary endpoint, secondary endpoint, or different

endpoint.

They said no way. You are going to violate the multiple comparison principle. It's not for me -- you know, for me only, sir. It's actually fundamental issue of the statistical methods, right.

If you look at so many things all together, and even there is nothing cooking, nothing going on, by chance, if you use the same rule, like a .05 as a threshold value, we actually have lot of misinformative result or misleading conclusions.

That's what my point.

BY MR. NIGH:

Q. All right. Well --

A. It's not only for -- it's actually from other agencies. And you can check easily, you know, the FDA's website. The book I cited by Furberg, right, you just mentioned this book,

right. Everyone is worried about the multiple comparison issues.

Q. Well, I'm glad you raised that. You raised two different references or two different societies, the FDA and The New England Journal of Medicine, correct?

A. Yes, sir.

Q. Now, aren't you aware that the FDA says that it's improper to use Bonferroni when looking at safety issues?

MR. MERRELL: Objection to form.

THE WITNESS: I don't know exactly what FDA's principle of looking at safety endpoint with a document or not. I don't know.

BY MR. NIGH:

Q. Do you recall -- you just told me the FDA when they're looking at the principle of drug approval, that they will use multiplicity. But do you realize the FDA has actually condemned the use of Bonferroni when looking at

safety issues?

A. Well, I think what I'm trying to say for most NDA, which is new drug applications, FDA insist that we need to apply a multiple -- the adjustment, comparison adjustment.

I believe in some trials they use safety endpoint, which is no surprise. For example, you want to study anti-diabetes drug, the heart attack, stroke, CV death are the safety endpoint, right. So in that case, it's a safety endpoint.

And I believe FDA also insists that you needed to make adjustment for multiple comparisons.

Q. So you're not aware then that the FDA has said that it's improper to use Bonferroni multiplicity testing when looking at safety issues? Do you know one way or the other?

MR. MERRELL: Objection to form.

THE WITNESS: I said -- sir,

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anti-diabetes drug, you usually would want to conduct a safety trial to see the anti-diabetic the drug would increase the MI, stroke, or CV death. That's actually the safety endpoint.

And for this endpoint, everybody knows what's called, MACE, M-A-C-E, the major cardiology -- cardiovascular event, and we do need a multiple comparison.

I believe in FDA's position, they also like to have the multiple comparisons.

But for your case, for example, valsartan impurity, I'm not for sure FDA has experienced dealing with this kind of situation yet. It's pretty new, right. So I don't know what their position, is.

I cannot speak with FDA. I am not expert in regulatory

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science. I just use my basic statistical principle to share with you, even for safety endpoint, if you don't take care with the multiple comparison, we're going to have a lot of false positive claims.

That means the treatment probably is safe, but because you don't make adjustment, you find a lot of toxicity models.

So that's a concern, right. It's not really separated from efficacy endpoint from a safety endpoint. I believe we should apply similar principle to safety and efficacy endpoint altogether.

BY MR. NIGH:

Q. I understand your opinion is that you should apply multiplicity to safety endpoints. I'm not asking you about that.

You raised the FDA as one of your references. I'm now asking you

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about the FDA and Bonferroni specifically.

Hasn't the FDA weighed in, or are you aware of whether or not the FDA has weighed in on whether or not it's inappropriate to use Bonferroni when looking at safety issues?

A. I don't know, sir. We've already explored the Bonferroni adjustment has been used by FDA regulatory people. We can find out.

Q. But I'm here today asking you. You raised FDA, and I'm here today asking you about your opinions.

You haven't seen anything where the FDA says it's okay to use Bonferroni for safety issues, correct?

MR. MERRELL: Objection to form.

THE WITNESS: Well, I said it for antidiabetes drug, they may use a safety endpoint. That's one example.

BY MR. NIGH:

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Q. In terms of the New England Journal of Medicine, have you seen multiple studies that have criticized using Bonferroni adjustment for safety issues?

MR. MERRELL: Objection to form.

THE WITNESS: I cannot speak with New England Journal of Medicine. They just issue a guideline for statistical analysis. They said, well, all the endpoints. They didn't say efficacy or safety endpoint by the way, which we can go on the website and look, right, to look at carefully.

They are simply saying, look, you have one study, you have to tell me for primary endpoint which is safety or efficacy.

I don't know exactly the language they use. But they say for primary analysis, you utilize

the P-value. Pre-specify the level you want it to. Then the next level for secondary endpoint, you are not allowed to apply the same principle, .05 anymore to claim for the secondary endpoint, there is issue or not. That's my understanding.

BY MR. NIGH:

Q. I'm sorry, it's your understanding that for a secondary endpoint that The New England Journal of Medicine says that you're no longer allowed to apply .05 for as your P-value for the secondary endpoint. That's your testimony?

MR. MERRELL: Objection to form.

THE WITNESS: They don't -- they don't allow you to report in the P-value anymore.

BY MR. NIGH:

Q. Okay. But when they report as the secondary endpoint, they still

show the confidence intervals for those secondary endpoints at a 95 percent confidence interval. Right?

A. Yeah, the confidence interval contains more information than the P-value --

Q. Right.

A. -- the size difference.

Q. But the confidence interval reflects the P-value. In other words, if you can see in that confidence, 95 percent confidence interval that it doesn't cross one, then you know you have a P-value less than .05, correct?

A. Well, if you want to interpret it that way, you can do that. But confidence interval would provide you more information than across the boundary, null value or not, right? You can tell me how big the confidence interval is. If it's too wide, you know you don't have enough information to tell the truth, right?

If the size of the estimate,

like in this case, odds ratio or relative risk is very small, you say, well, you know, you have a large trial and thousands, thousands of patients in cardiovascular trial, right. And no matter what, how low your odds ratio, like 1.01, you still have a statistical significance. Your confidence interval still excluded here, one, for example, odds ratio, but the question is, is that really interesting physically or clinically speaking. Right? That's confidence interval will tell you, right.

It's much more information than just simply P less than .05.

Q. Okay. When I asked you about multiplicity and Bonferroni, you raised FDA and you raised New England Journal of Medicine. I'm only talking now for this question, multiplicity and the use of Bonferroni.

Do you believe the FDA and The New England Journal of Medicine support the use of Bonferroni as when it

comes to safety issues?

A. Sir, I give you one example for MACE event. I do understand, I repeat it three times for you. That's a safety endpoint.

Q. Have you --

A. Do you understand what I'm trying to say, sir? I mean --

Q. I do.

A. -- it's a MACE -- okay.

So why don't you take that example and if we actually can get the FDA, being the review for the past five years, let's think about how many FDA is concerning about the safety endpoint, right. How do they handle the safety endpoint. But I don't know the detail at all, right.

I am just sharing with you, sir, based on my experience dealing with FDA, they don't want us to apply P less than .05 for every endpoint.

I don't know if they restrict at the efficacy endpoint and

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they don't care about the safety endpoint, I don't know their positions, sir. This is a principle we do. Personally, as you know well, I set up for safety and efficacy endpoints together. We need it to be helpful, right. Don't make a large, very large unacceptable false positive rate.

For example, let me give one -- ten seconds, give you one example. If you have three studies, right, independent study, if you apply the P less than .05, clearly there is an issue, right.

Then apply the three clinical trials independently, the false positive rate will become 14 percent instead of 5 percent anymore.

I say well, do you really think 14 percent is acceptable to be the false positive rate, which to me is very high, right.

You can apply the safety endpoint here too. If you say three

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studies, study the efficacy issue, well, let's apply .05 for each study. If there is study, P-value less than .05, then let's be clear, there is a safety issue.

I said, sir, wait a second, if you apply this principle, you are going to make a mistake. 14 percent is -- 14.5 percent by the way, okay, to make a mistake. Claim something unsafe. But actually the drug is safe.

Do you think that's acceptable? If you think acceptable, or society, or FDA accept it. Well, I have no argument, that's their position, right. I just share with you my experience with FDA and also New England Journal of Medicine.

Q. I'm not asking about, you know, just multiplicity issues at this point. My question is simply Bonferroni now for this question.

Are you aware that the FDA has criticized the use of Bonferroni when looking at multiplicity issues?

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A. FDA, I don't think that they criticize using Bonferroni, right. Bonferroni may be applicable to efficacy endpoint and they probably little bit of liberal for the safety.

But my point is that I don't know how liberal you want allow safety say, well, forget about any adjustment.

By the way, Bonferroni adjustment is just one adjustment. You can have other adjustment. You don't have to stay with Bonferroni adjustment.

The principle is a multiple comparison issue. Do you think that there is a problem applied the same rule for every single endpoint for every study, right, with the same P less than .05. I said well, be careful. This could be a lot of misleading conclusions. That's what I'm trying to say, right. Nobody would argue with me. You cannot do that. Even Dr. Madigan cannot dispute, say, well, there is a higher, much higher unacceptable false positive

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rate if you don't take care of multiple comparison problem. He just argue, say, well, maybe for safety you can relax a little bit. The question is how much relaxation you are waiting to do for safety endpoint, right. We don't know.

You know, you can ask Dr. Madigan's opinion. Do you think he say, well, forget about any adjustment. Just stay with .05, for anything, for safety. Do you think that is okay or it is not okay? Well, I'm not in position to educate Dr. Madigan. He knows this very well.

Q. I didn't ask you about Dr. Madigan. I simply -- and you gave me a lot of information that I didn't ask about.

So what I asked was, are you aware that the FDA has criticized the use of Bonferroni when looking at multiplicity issues related to safety.

MR. MERRELL: Objection to form.

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THE WITNESS: I think FDA would ask us to make multiple comparison adjustment. Bonferroni just one of the tool to make adjustments, sir. Okay. If you --

BY MR. NIGH:

Q. I think --

A. Specifically if you want to put your words in my mouth, if you think FDA against to using Bonferroni adjustment, I say no, they don't have any document saying that you cannot use Bonferroni adjustment.

If you have some document issued by FDA saying Bonferroni adjustment is no good, I will be willing to learn. Everyday I learn something brand new, which is nothing new to me, right. We should learn something new.

So if you say somebody saying, FDA saying no, you shouldn't do Bonferroni adjustment at all for safety. That's fine. That's their opinion,

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right.

I said, well, look, whatever you want to claim, that's regulatory agency's claim. I just speak for myself. I say, well, my experience with FDA they want to make multiple comparison adjustment.

But you say, are they against using Bonferroni. I said well, where is any document. They say we don't like Bonferroni adjustment for safety endpoint. If you have this document I'd be very happy to read it, sir.

Q. It sounds to me from that answer that you're not aware of any document or any situation where the FDA has criticized the use of Bonferroni when looking at safety issues; is that correct?

A. Well, that's my knowledge. I don't know where and when the FDA has this issued such a statement or position, right. I don't know, sir.

Q. Now let's take a look at --

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let's talk about New England Journal of Medicine. Are you aware of studies that criticize the use of Bonferroni when looking at safety issues?

MR. MERRELL: Objection to form.

THE WITNESS: I don't know offhand right now any paper they criticize. I think the best way, we can go to the website of New England Journal of Medicine, right. They have so-called guidance for statistical analysis.

I know most associate editors of statistics in New England Journal of Medicine, they all my colleagues at Harvard, right, so we can easily get their opinion and say what is the position of New England Journal of Medicine, right.

But first, sir, you can Google their website. They have clearly stated what we should do

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from now on handling this secondary endpoint.

Like you said very well, we use confidence interval, insert a P-value, right. I think that is one step improve our scientific investigation.

The P-value is useless information for us. Maybe pass the first hurdle. But then after pass the first hurdle, you ask yourself, how do you interpret clinical utility of your findings, right, instead of telling me the P-value is .04.

BY MR. NIGH:

Q. My question, was let's talk about The New England Journal of Medicine. Are you aware of studies in The New England Journal of Medicine that criticize the use of Bonferroni when looking at safety issues?

MR. MERRELL: Objection to form.

THE WITNESS: So I said many times, I don't have the paper right now I can show that to you. But the best way to go into the website to look for the guidance, right.

BY MR. NIGH:

Q. It sounds to me like you're not aware of any journal articles or studies in The New England Journal of Medicine that criticize the use of Bonferroni when looking at safety issues; is that correct?

A. Well, I don't know any paper I know. But I'd be happy to learn.

Q. When you put your expert report together, where you insisted upon the use of Bonferroni for the data in valsartan, did you do any research to see whether or not that has now been criticized in journal articles, or by regulatory agencies when looking at safety?

MR. MERRELL: Objection to

form.

THE WITNESS: Well, that was not in my assignment. As you noted very well, in several of my reports, in the legal cases, I raised the same issue, right. I said well, be careful to interpret the safety issue. Because this multiplicity.

I don't think Bonferroni is really important role here. Bonferroni is just one of the tools. If we are smart enough, we can figure out another way to make adjustments, right. Not using Bonferroni adjustment.

Bonferroni adjustment some people say maybe a little bit conservative. I say well, that's okay. Some say you have a way to make adjustment for multiple comparison, please do it, right. At least so we can see it.

And instead of a one-way

street, don't make any adjustment. For me that's not very good.

BY MR. NIGH:

Q. You commonly raise Bonferroni as your go-to multiplicity in many of your expert reports, correct?

A. Yeah. That's the obvious way, straightforward way to handle multiple comparisons, sir.

Q. Well, actually false discovery rate is used much more often. False discovery rate computations are used much more often when looking at safety issues than Bonferroni, correct?

A. I don't know much about discovery rate, sir. That's another school of thought. And I think that they are essentially equivalent to using P-value. Just using different scale.

Q. And also Fisher pooling is one of the more -- much more common ways of looking -- or looking at multiplicity across clinical studies, correct?

A. No, sir --

MR. MERRELL: Objection --

MR. NIGH: Sorry. Let's strike that question. Sorry. Strike that question, please.

THE WITNESS: Okay.

BY MR. NIGH:

Q. And also Fisher pooling is used much more often when looking at safety issues than Bonferroni, correct?

A. No, sir. You misunderstand Fisher pooling P-value now. Fisher P-value pooling is very similar to meta-analysis. They have several studies, each study has a P-value. They wound up pooling that P-value across several studies, getting a global P-value. Okay. So that's similar to methodology now.

So the -- you raise the multiple comparison, is not really similar to meta-analyses.

So, I'm sorry, I probably missed your point. But a pooling, Fisher's pooling is quite different

compared with multiple comparison problem.
Q. Fisher pooling allows you to look at the rates of effect across a collection of studies, correct?
A. Yeah. That meta-analysis, essentially.
Q. It's similar to a meta-analysis, correct?
A. Yeah. So it is orange and apples you are talking about here now, right. Before you are talking about multiple studies looking individually. Now you say wait a minute, let me pool it all together now. That's a different way to answer your question, right.
Q. Those are both -- those are both ways to look at false positive rate. You can look at Fisher pooling across a pool of studies to look to see if that Fisher pool rate still shows an effect for the question and answer, correct?
A. That's a meta-analysis, sir.
Q. Now, you didn't choose to do

a false positive rate in your opinion at all, correct?
A. No. Because it didn't matter considering the discovery rate. My assignment is not really creating new animals for you guys to evaluate, right. So I stay with the P-value Dr. Madigan used.
Q. My problem here, I actually worded the question wrong.
You didn't choose to do a false discovery rate in your opinion at all, correct?
A. Because Dr. Madigan didn't do that either.
Q. In fact, you chose the most conservative or what has been widely criticized for safety issues as the most conservative approach for multiplicity, for measuring multiplicity, correct?
MR. MERRELL: Objection to form.
THE WITNESS: Sir, I don't -- I don't understand your

language. Why do we criticize the Bonferroni adjustment? What is the -- what are you talking about, why are you criticize?
BY MR. NIGH:
Q. Sir, again, you haven't reviewed any studies that criticize using Bonferroni? Not even just in the New England Journal of Medicine. But that criticize using the Bonferroni adjustment when looking at multiplicity issues. You haven't reviewed studies on that in regards to safety?
A. Well, sir, you have a different school of thought, right, in statistics even. This is like your legal profession. There are so many different ways to actually make a decision, right.
People have a different way to make adjustment for multiple comparisons.
You know, Bonferroni is one of this, right. Obvious, straightforward, commonly used adjustment

tool. You can use the other adjustment, right, if you wanted to.
I just choose one to illustrate, this can be problematic if you don't make multiple adjustment. So my point is that multiple comparison adjustment, I'm not to say you should have used always a Bonferroni adjustment. If you don't like Bonferroni adjustment, you can use alternative way.
But the question is, should the way take care of multiple comparison problem or not. That's the issue.
Q. Right. You chose, in terms of your example, Bonferroni, which would actually be the most conservative way of looking at multiplicity, a/k/a, the friendliest measure to pharmaceutical companies when it comes to looking at safety issues, right?
A. I'm not for sure when you say conservativeness, this is just one of the tools, sir. I repeat it so many times. I said you don't have to use

Bonferroni adjustment. My point is you have to make some adjustment. I just give you example.

If you use Bonferroni adjustment, then what kind of threshold value you should use, right. If you have a smaller smarter way to handle multiple comparison problem, I have no issue, sir. At least you have to address this issue of multiple comparison, right. It doesn't matter if it is an efficacy endpoint or safety endpoint, right. Both are very important to us. You don't want to criticize the impurity in valsartan has some issues.

If you look at 100 studies, just happen to say one study show up with a P-value less than .05, you say wow, look, this is evidence. It can be helpful to interpret this, right, because you're looking so many studies both together, right.

If you stay with the same rule for each study, you are going to

make some wrong conclusions. That's what I said in my report.

I didn't say you have to use Bonferroni. I just say if you use the Bonferroni, this is the threshold value you should use, right.

If you disagree with this approach, that's fine. But my point is you should make some adjustment, right.

Q. The example that you give in many of your expert reports, Bonferroni, would actually be the most conservative way of looking at multiplicity, a/k/a the friendliest measure to pharmaceutical companies when it comes to looking at safety issues, correct?

MR. MERRELL: Objection to form.

THE WITNESS: Well, I'm not quite sure if this is most conservative way to do it. I don't know. Maybe. But I'm -- will be very happy to learn what is alternative way to dealing with

your present case, right, handling multiple comparisons.

BY MR. NIGH:

Q. Have you not seen numerous studies talking about using false discovery rates instead of Bonferroni when discussing safety issues?

A. Well, there are some. But again, I said before, sir, Dr. Madigan didn't use discovery rate. So he used the P-value, right. So my assignment say could you actually review what Dr. Madigan did in his report. That's what I'm responding to the report.

I'm not -- I was not in the position to create another quantity for discovery rate. And because Dr. Madigan didn't use it, why should I bother to go to that route.

Q. Well, what you've done is you've cherry-picked the most conservative measure, Bonferroni, when looking -- as an example, when looking at multiplicity issues. And this is the

same cherry-picking you've done for many of your past expert reports, just looking at Bonferroni as opposed to other measures of multiplicity.

MR. MERRELL: Objection to form.

THE WITNESS: I strongly disagree with your word "cherry-picking." I didn't look at the data to choose my procedure, right. That's what you call cherry-picking.

I actually -- before I even had Dr. Madigan report, I said you should make some adjustment. Bonferroni is one of the tool, right. That's not a cherry-pick answer. That's pre-specified, right.

If you disagree with me about Bonferroni adjustment, that's fine. Nobody said that you cannot do that.

My point in my report, I say

you need to make some adjustment for multiple comparison. If you can show us through the discovery rate to say, oh, this is a better way to make adjustment, I say fine, let's look at it, right. Present it to us. We're going to look at it.

BY MR. NIGH:

Q. You gave an example earlier where you talked about three studies, and if there was a, you know, P-value of .05.

And you said your chances of getting one out of those three studies would be 14 percent. Do you remember that example?

A. Yes, sir. It's in my report by the way.

Q. Right.

What are the chances of two, if two of the three had a positive finding, what would those chances be?

A. Oh, it's very easy to do. It's 1 minus .95 times .95. If you had a

calculator, you can do very quickly.

Q. Right. When you're looking at more than one positive rate, there's a way to calculate that fairly quickly, right?

A. Yeah.

Q. Okay. It's no longer 14 percent at that point, correct?

A. Yeah. If you have two studies, I don't know, it's maybe 10 percent instead of 5 percent, right. If you have four studies, then suddenly it become 20 percent, right. So the more study that you're looking at, the higher the positive rate now.

Q. Right. But you're telling me right now -- I mean two positive results. I'm not talking about one positive out of three. Two positives out of three.

Wouldn't that be important to measure, that -- if you had two out of three, that's a different measurement than one out of three in terms of

measuring the effect, though, right?

A. Yeah, that's a fair -- that's a fair question. But my position is not really say out of the three there are two truly positive result, right, supposedly.

Now, you are asking me, say, what is the point error now. This is a very interesting question now, right. You say well, your null hypothesis go along with -- the three trials are really -- are not null, right, meaning there's no difference between the two groups. I said, well, at least the one guy, he's talking it up, he's saying what is the chance, I say 14 percent. Then you said, what is the chance if two guys popped up. I don't know. We have to sit down and figure this out.

Q. Right. When you're looking at Bonferroni, Bonferroni is focused, in terms of its math and its ideals, when thinking about one false positive out of a collection of studies, correct?

A. Yeah. At least one. You pop it up, you claim positive.

Q. But when there's two or more, that's one of the main criticisms of Bonferroni, is that dividing the P-value by the number of studies, when there's two or more positive findings, would cause Bonferroni to be much too conservative, right?

A. Sir, you actually changing the questions now, right.

My point I say in my report, I said it would be helpful when you're dealing with multiple studies, multiple endpoints, to help with multiplicity issue.

I give you one example. I said, well, if there is no difference across all the studies, all the endpoints, right, what is the chance you're going to claim something is positive. I said this is the number, right. But if you say wait a minute, I'm changing my story now. I say out of

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three study, I have two positive, more than .05, then you're asking me, say hey, what is the false positive rate now. You know, that change the story now, right.

You can go on forever. You can say three positive out of three, that is a different story now. That is not exactly what I said in my report.

Q. I understand it's not what you put in your report. You gave the hypothetical of one out of three.

My point is, when it's two out of three, it changes the findings dramatically, it's no longer 14 percent. It's much, much higher -- I mean much, much lower that those chances would happen, that you'd get two out of three by chance when the P-values -- two out of three studies have a P-value of less than .05. That'd be much lower than 14 percent, correct?

A. Yeah, that's a fair thing to say, yes.

Q. In fact, you can do it off

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the top of your head, but that would actually be much less to get two out of three that are .05 or less, that -- that chances of that pool would actually be less than .05?

A. I don't know the mathematics, sir. You are too smart for me to calculate it so quickly. I don't know.

Q. Well, when you're looking at a rare event, and most of the -- when you're looking at a rare event of something less than .05 and most of the events in a pooled data are coming up positive as that rare event, in that study, we know then that the -- when you calculate a pool of data, that it's going to be lower than the initial .05, right? I mean that's just a general statistic, general statistics statement.

A. Yes, you are absolutely right. If everything go to the direction you like, right, you're combining several studies, of course, you can enhance your

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argument. Unfortunately, if you look at all the meta-analysis Dr. Madigan cited, on the left-hand side, right-hand side of null value, right, back and forth, back and forth. And it turns out the odds ratio is really not that interesting, 1.2, you know, something lower than 2, and, you know, that's the issue, right. You're combining the negative study with a positive study, hopefully the positive study will dominate in your result. You know, people can play all kinds of games, right. I mean, it's unfortunate, right.

Q. You know, right now I wasn't asking about Madigan's report. But it's interesting that you brought that, because you just brought up the meta-analysis.

Let's set gastric cancer aside in terms of the dietary studies. Let's actually focus on lung cancer.

Did you have an opinion on the lung cancer dietary studies?

A. Can you show me the report

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so I can refresh my memory?

Q. Well, lung cancer had an effect size of 3.1, P-value of less than .001 in the De Stefani study. Goodman, for men, had an effect of 3.3, P value of .006 for males. For females, Goodman had an effect size of 2.7, .004. And then for Lowe, effect size of 1.1, P-value of .6.

So can't you look at that data and immediately realize that the pooling of that data would be less -- a P-value of less than .05?

A. You are putting all the study together you're saying, sir?

Q. Yes. For lung.

A. Are they -- sorry, are they pretty much in a similar population or are they different population?

Q. Well, do you know?

A. Sorry, sir?

Q. Do you know?

A. Say it again?

Q. Do you know?

A. I don't -- I don't know. You just raised the issue. I didn't raise it, you know, saying that checking every study they are similar or not. The meta-analysis are combining.

First thing you need to say, well, you know, they are combinable, right. Some actual studies it is not combinable. So -- but people actually just are lumping all the orange and all -- the apples altogether, right, getting a summary of statistics. And using that summary of statistics in a not right way in my opinion, right. So you can combine it any way you want it to.

The things that are if you have any negative trial for lung cancer, yes, you do have, right, but if you are only picking up the highly significant event reporting to us, I don't know. Because Dr. Madigan didn't show all the negative trials in the lung cancer, right.

Q. I'm sorry, do you believe

there is another study that is negative for dietary studies for lung cancer other than what he reported?

A. You just said -- the last one, 1.1 or some alteration, you just told me.

Q. You give that a negative, that's still an increase, it's more than one, correct?

A. Sorry, sir. Using the P-value of what, .6, something like that?

Q. .6. Yeah, 1.1 is still an increased risk.

A. Oh boy, I tell you, you mixed the fundamental issue about the inference of statistics, right. You cannot say my point estimate is 1.1, I've got a problem, right. Besides you have those observational study, 1.1 odds ratio can be easily changed to less than one if you use different confounders in adjustment. Everybody knows that.

You have measurable confounders. If you just happen to

measure those confounders, suddenly odds ratio could be .8, .7. So the very low odds ratio really doesn't carry too much weight, right.

That's why -- you guys have a very interesting book. I know you know this book very well. Called scientific evidence, right, for lawyers, something like that.

In that book, actually it is written by a lawyer actually many years ago. He say, okay, this is our Bible. I look at it, it's very interesting.

If the odds ratio is less than two, the guy said forget it, I'm not interested. I ask the lawyer, hey, why are you using the threshold number two? I said, listen, this is observational study is all messed up already. You make all kinds of adjustment. If you use a different adjustment, if we can lower odds ratio point estimate like you say, 1.1, right, I can easily swing around, right.

But if you have like five or six odds ratio, then we don't have the problem of robustness of your data. This actually, sir, this is the first principle of the so-called Bradford Hill criterion, right, for causation.

First one is that you need to worry about the size of effect. Not just like the P-value, right.

Q. You referred to it as a negative study, that's why I asked you, but negative would mean below one, in terms of effect size when it comes to statistics, correct?

A. I would say it's a neutral study. It's not really called a negative.

Q. That's the reason I raised it. I don't disagree with you about the amount of rate -- amount of weight to be given to the effect size. I raised it because you used the word "negative study," right?

A. Okay, sorry. I apologize.

I use a negative word.
Q. 1.1 is technically an increased risk, not statistically significant in the study but it's still technically an increased risk, correct? I'm not talking about what inference to be drawn from it.
A. Well, if you don't have an inference, then we just go home today. You don't have to worry about anything anymore, right. Everything based on point estimate, you make a decision, you say wow, is that okay, judge. You can ask the court.
Q. So you have three studies. One is a 1.1 increased risk, not statistically significant.
The De Stefani 3.1, more than a doubling of the risk statistically significant with a P-value of less than .001. And the other one, 3.3 increased risk effect size with the P-value of .0006.
You take those three

studies, how do you view those three studies together?
A. How do I -- how do I do that?
Q. Yes. How do you view those three studies together?
A. If I -- if I truly believe those studies are well conducted and they considered all the confounders, adjustment, and it's a prospective -- now be careful of the word "prospective," right, it's not a risk factor. Okay? Then I would say, yes, there's some strong signal to show us, right, for this case.
I don't believe those studies are prospective. Maybe I'm wrong. But if my memory tells me they were not prospective. Okay.
Q. You don't believe that the De Stefani or Goodman studies were prospective studies?
A. Say it again, I'm sorry, sir.

Q. You don't believe that the De Stefani or the Goodman -- the De Stefani lung dietary study and the Goodman dietary study that Dr. Madigan cited, you don't believe that those were actually prospective studies?
A. Well, we can check easily. If you put on the papers on the screen we can look very carefully --
Q. I'm asking you -- you viewed these studies. I'm asking you your knowledge, before we look at the studies, you don't believe that those were prospective studies?
A. Well, I cannot say yes or no. But we can easily check.
Q. How about colorectal cancer. You get a study that shows 2.1 increased risk. You get another study that shows 1.5 increased risk, P-value of .001, and another study that shows 1.4 increased risk, P-value .005.
How do you compare those studies as a pool of studies?

MR. MERRELL: Objection to form.
BY MR. NIGH:
Q. Those results?
A. I would -- I would say the same thing, sir. It is well conducted, well balanced with a start of baseline factors, prospectively I then would agree with you, there is some signal indicated, there is a chance the incidence increase, right.
Q. Okay. Let's go back to the two studies, I mean the two reports on the screen.
Okay. We were in Number 31. And I draw your attention down to using the 5 percent rule. If we can go down to Taxotere on the right side using the 5 percent rule. Yep.
On the valsartan side, you put "Using the 5 percent rule for claiming statistical significance to analyze simultaneously a large number of tests in a study will yield a high rate

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of false positive findings." On the right side, you put "Using the 5 percent rule for claiming statistical significance to analyze simultaneously a large number of safety endpoints in a study will yield a high rate of false positive findings."

Those are identical sentences in the two reports, correct?

A. Yes, sir.

Q. Next it says, "Often the overall false positive rate could be as high as 20 percent or more. That is, a very high chance of finding an exposure is not safe with respect to control when, in fact, there is no difference between the two groups."

Let's take a look at Number 32. You have -- and let's go to Paragraph 19 for Taxotere. "A standard procedure to handle the multiple comparison issue is to use the Bonferroni adjustment."

That's what you put in

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valsartan.

And in Taxotere you put "A standard procedure to handle the multiple comparison issue is to use the Bonferroni adjustment."

Those are identical sentences, correct?

A. Yep.

Q. Next you put, "For example if there are 50 different types of tests conducted, the false positive rate is 5 percent, then for each individual test we should use a false positive rate of .1 percent, 5 percent divided by 50, to assess whether there is a potential signal on the safety issue" -- "safety concern."

On the other report you put, "For example, there are 50 different types of adverse events considered in the trial. If the total false positive rate is 5 percent, then for each individual adverse event we should use a false positive rate of .1 percent, 5 percent

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divided by 50, to assess whether there is a potential safety" -- "there is a potential signal on the safety concern."

Those are identical sentences, correct?

A. Yep.

Q. I'm sorry, I missed the very first sentence, which says, "A standard procedure to handle the multiple" -- oh no. We went over that.

Next is "The corresponding confidence interval level should be 99.89 percent, which is 100 percent minus 1 percent" -- or ".1 percent."

And on the other report you say, "The corresponding confidence interval level should be 99.9 percent (100 percent minus .1 percent.)"

Those are identical sentences, correct?

A. Yes, sir.

Q. Turning to Paragraph 33, and Paragraph 20, the next paragraph. The next paragraph in valsartan, and then the

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next paragraph in Taxotere.

Next you have "The problem of inflation of a Type I error or positive" -- "false positive rate becomes much worse when we examine the results of several independent clinical studies at the same time with a Type I error rate of .05 for each study."

In Taxotere you put "The problem of inflation of a Type I error or false positive rate becomes much worse when we examine the results of several independent clinical trials of the same type with a Type I error rate of .05 for each study."

Those are identical sentences, correct?

A. Yep.

Q. In valsartan you put "For example, suppose there are three independent studies which compare the exposure group with control."

In Taxotere you put "For example, suppose there are two

independent studies which compare Taxotere."

Do you see that?

A. Yep.

Q. Similar but you've gone to three in valsartan instead of two in Taxotere, correct?

A. Sorry, sir, I missed what you are saying.

Q. I said similar sentences except for you've gone with three in your hypothetical for valsartan and two in your hypothetical for Taxotere, correct?

A. Yep.

Q. The next sentence is "Suppose that we claim that there is a statistical significant difference between these two groups when the P-value of any one of these three trials is less than .05."

In Taxotere you put "Suppose that we claim there is a significant difference between these two groups P-value of any of these two trials is

less than .05."

Almost identical except for you use three in -- three trials in valsartan and you used two trials in Taxotere, correct?

A. Yeah. Because Taxotere only has two clinical trials available at that time.

Q. I see.

Next you put, "If we apply this decision rule, the total Type I error rate would be 14.3 percent. That is, even if there were no differences between the exposure and control with respect to cancer incidence, the chance of claiming either the exposed or control is harmful is more than 14.3 percent."

In Taxotere you put, "If we apply this decision rule, the total Type I error rate would be 9.75 percent. That is, even if there were no differences between Taxotere and control with respect to alopecia events, the chance of claiming either Taxotere or

control is harmful is more than "9.75 percent in at least one study."

Correct?

A. Yep.

Q. Those sentences are fairly similar, except for in valsartan you're looking at the hypothetical of three trials, and in Taxotere you're looking at the hypothetical of two trials, correct?

A. Yep.

Q. Interesting that you use the same word "trials" for both valsartan and Taxotere when valsartan doesn't have any clinical trials.

Why did you use the word "trial" there?

A. A trial and the study, I use interchangeable.

Q. I see.

So in a observation study you would call those trials?

A. Well, it depend on your definition of a trial, right. If it a trial, if it's a experimental study

prospective, and observational, we don't call it observational trial, we call it observational study.

Q. Well, there are no experimental study prospectives in -- strike that.

Next is, "This problem is compounded if we apply the same rule to a large number of studies."

And in Taxotere, you put the same statement, exact same statement, "This problem is compounded if we apply the same rule to a large number of studies," correct?

A. Yep.

Q. And next you put, "Therefore, when we analyze multiple studies and statistical tests simultaneously, any conclusion of toxicity must be carefully interpreted due to the multiplicity of tests."

On the other side you put, "Therefore, when we analyze multiple studies simultaneously, any conclusion of

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toxicity has to be carefully interpreted."

Those are similar sentences, correct?

A. Yeah. I like to point out, you see the words I use, "carefully interpreted," right.

I didn't say you have to do Bonferroni or not.

I just say, you have to be carefully interpreted.

Q. Okay.

MR. MERRELL: Counsel, I just wanted to talk about lunch. We're getting sort of close to the lunch hour. I don't know what you have, if you're moving to something else or what times makes sense.

MR. NIGH: I think right now is a good time to take a break. How long do you guys want for lunch?

THE VIDEOGRAPHER: The time

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right now is 12:20 p.m. We are off the record.

- - -

(Whereupon, a luncheon recess was taken.)

- - -

THE VIDEOGRAPHER: The time right now is 1:17 p.m. We're back on the record.

MR. NIGH: Okay. Let's pull up LP-1562, your Celebrex report. And let's put that side by side with your valsartan report.

BY MR. NIGH:

Q. We'll do similar what we did with Taxotere.

First, though, in Celebrex, Dr. Madigan wasn't on the opposite side of you in Celebrex, correct?

A. Honestly, I don't remember. Sorry.

Q. Do you remember who was on the opposite side of you on Celebrex?

A. If I read in my report, I

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can refresh my memory. Right now I'm not quite sure.

Q. Does Dr. Milton Packer give you an indication? Does that sound familiar?

A. Milton Packer is our side, is not opposite side.

Q. Oh, he's on your side. Okay.

A. Yeah.

Q. But you don't recall who was on the opposite side of you in Celebrex, correct?

A. I think probably Dr. Nick Jewel was one of those guys.

Q. Who did you say?

A. Nick Jewel out of Berkeley. University of California, in Berkeley campus. J-E-W-E-L.

Q. Okay. But you don't recall Dr. Madigan being on the opposite side of you in Celebrex, correct?

A. I vaguely remember he was. But, you know, I'm not quite sure.

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Q. Okay. Let's take a look at your report side by side with Celebrex.

Now, in Celebrex, you were also -- just like in Taxotere and for valsartan, you were also retained by the defendants who were pharmaceutical companies in each -- in Celebrex as well, correct?

A. Yes.

Q. Okay. Looking at the screen, remember we talked about the Celebrex report, we can pull that up so we can quickly see it here. We looked at this earlier today.

Do you recall that?

A. Yes, sir.

Q. Okay. Celebrex report, that's dated March 30th, 2007. So that's over 14 years ago, 14 and a half years ago, correct?

A. Yeah.

Q. Okay. Let's go to paragraph 17 in valsartan. Let's look at Paragraph 8 in Celebrex. We'll do what we did

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before, look at the side-by-side comparisons.

Okay. Valsartan says, "Suppose that we were interested in a rate of occurrence" -- "Suppose that we were interested in the rate of occurrence of a certain clinical event, for example cancer, among subjects exposed to NDMA or NDEA to their counterparts (control)."

Next number for Celebrex, 14 and a half years ago, you put, "Suppose that we are interested in the incidence rate of a certain clinical event, for example CV events, among patients treated with Celebrex relative to the corresponding rate for patients who have been exposed to the drug."

Those are similar sentences, correct?

A. Yeah. I believe this is using the same statistical principle, right, dealing with a similar case.

Q. Sure. The next sentence says, "In the first step we take a sample

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from a population of subjects exposed and another sample from the population of subjects who were not exposed."

Your next sentence in Celebrex says, "To do this, we take a sample from a population of patients treated with Celebrex and another sample from the population of patients who did not receive Celebrex."

Similar sentences, correct?

A. You know, by changing a word, right. You're in the first step now, right.

Q. I recognize you changed a word.

The next sentence says, "Assuming that these samples are valid representatives of the two populations, quantitative analytic methods can be used to determine whether the exposed group has higher, lower, or similar event rate than for the control group."

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Your sentence in Celebrex starts off the same way, "Assuming that these samples are representative of the two populations, statistical methods can be used to determine whether the Celebrex group has a different rate of CV events than the non-Celebrex group."

Those are similar sentences, correct?

A. Yes.

Q. Next, it says, "Since we draw conclusions based on a subset of subjects, any qualitative or quantitative interpretation of the result, i.e., whether the rate is higher or not, is subject to sampling error."

On the other one, you say, "Since we draw conclusions based on a subset of patients only, the" -- "any qualitative or quantitative interpretation of the result, i.e., whether the rate is higher or not, is subject to so-called sampling error."

Very similar sentences,

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correct?

A. Yes, sir.

Q. In valsartan, you put, "That is, the observed event rate may be higher leading to a false" -- "a possible false positive finding, or lower, leading to a possible false negative finding, than the true event rate in the population."

In Celebrex, you say, "In other words, the observed incidence rate may be higher, leading to a possible false positive finding, or lower, leading to a possible false negative finding, than the true incidence rate in the population."

Very similar sentences in the two expert reports, correct?

A. Yes, sir.

Q. Next you say, in valsartan, "An efficient statistical method for analyzing such data minimizes the chance of making these two types of error."

In your Celebrex report, 14 and a half years ago, you say, "An

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efficient statistical method for analyzing such data minimizes the chance of making these two types of errors."

Exact sentence in both of those, correct?

A. Is that wonderful? Because my principle is the same, right, for 14 years.

Q. I understand. Exact sentence in both of those reports, correct?

A. What's wrong with that, sir? I don't understand your point. You can go on for whole day to compare the notes. I'm not quite sure where we're going from here.

Q. Do you understand my question?

A. I understand your question perfectly. But I'm trying to say that the principle of statistical methods are valid. 20 years ago, today, they are the same old thing.

Q. I understand what you're --

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what you're saying. That's not my question.

A. Could I finish? Could I finish, please?

Q. Sure.

A. Can I explain that? Is that okay I finish?

Q. My question is, are those exact sentences in the two reports? What's your answer?

A. I responded to you, I'm glad that the same principle applied to several cases.

Q. So is your answer, yes, those are exact sentences in the two reports?

A. Yeah, no problem. It's all similar. They all the same. I don't even understand why you repeat everything, again, again, again.

Q. Next sentence, "It is important to know that, except for the exposure to NDMA or NDEA, the exposed subjects in the sample should be similar

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to the subjects in the non-exposed sample with respect to important observable or unobservable confounders."

In Celebrex, "It is important to know that, except for the usage of Celebrex, ideally the Celebrex users in the sample should be similar to the patients in the non-Celebrex sample with respect to important observable or unobservable confounders."

Gives two examples.

Those are very similar sentences again, correct?

A. Yep.

Q. Looking at the next -- Number 18. And looking at Paragraph Number 9. Looking at the next paragraph in valsartan and the next paragraph in Celebrex.

It says, "After we have determined how to draw" -- in valsartan, "After we have determined how to draw a valid sample from the population of interest, one has to determine what

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clinical endpoints are most appropriate to quantify the exposure effect."

In Celebrex, "Once an investigator has determined the patient population of interest, he or she must draw a valid sample from the population."

Similar sentence, correct?

A. Yep.

Q. Then you go down to, "Suppose that based" -- in valsartan. "Suppose that, based on the sample of 100 patients at the end of the study, four patients experienced such events."

In Celebrex, "Suppose that based on the sample of 100 patients, four patients experienced similar" -- "experienced CV events."

Similar statement, correct?

A. Well, one is for a CV event. The other one is cancer, isn't it? Are they different?

Q. They are very similar, aren't they?

A. Well, how do you define

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similar. I said this one case is for CV event. The right-hand side is for cancer incidence.

Q. You don't think that when it starts out -- the sentence says, "Suppose that, based on a sample of 100 patients," and the other one says, "Suppose that, based on the sample of 100 patients," and that for both hypotheticals, you assumed four patients that experienced an event, that those are similar sentences?

A. Well, whatever you say. It's similar. But I'm saying address different legal cases, right.

Q. Next sentence, "An obvious estimate of the event rate for the underlying population is .04 or 4 percent."

In Celebrex, "An obvious estimate of the incident rate of toxicity for the underlying population is .04, or 4 percent."

Those are very similar sentences, correct?

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A. Yep.

Q. Next sentence, "This is called a point estimate."

In Celebrex, exact sentence, "This is called a point estimate." Correct?

A. Yep.

Q. Next sentence in valsartan, "However, this estimate is based on a sample of patients."

Celebrex, "However, this answer" -- "this estimate is based on a relatively small set of patients."

Similar sentence, correct?

A. Yep.

Q. Next sentence, "The true event rate for the entire population may be more or less than 4 percent."

Next sentence in Celebrex, the true incidence rate for the entire population may be more or less than .04."

Very similar sentence, correct?

A. Yep.

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Q. Next sentence, "Different studies generating different samples may find a different" -- "may find different proportion of subjects with cancer."

Next sentence, "Another investigator using a different sample or study may find that none of the patients experienced a CV event."

The following sentence, "Therefore, when observing results from a single sample, it is important to attach a level of confidence to the observed point estimate."

In Celebrex, 14 and a half years ago, you put, "Therefore, when observing results from a single sample, it is important to attach a level of confidence to the observed point estimate."

Those are the exact same sentence, correct?

A. Yeah. I'm glad I am consistent.

Q. Looking at valsartan, "This

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quantitative scientific process is called drawing or making inferences about the true event rate."

In Celebrex, "This quantitative scientific process is called drawing inferences about the true incident rate."

Very similar sentences, correct?

A. Yep.

MR. NIGH: Turning to Number 19, and Paragraph 15 in Celebrex.

BY MR. NIGH:

Q. In valsartan, you start out, "Let me turn to the issues of comparing two groups of subjects, one having been exposed and the other being in the control."

In Celebrex, 14 and a half years ago, you say, "Let me turn to the issues of comparing two groups of patients, one receiving Celebrex and the other receiving a placebo."

Very similar sentences,

correct?
A. Mm-hmm. Yes.
Q. The next sentence, "To make sure the two samples of subjects are comparable with respect to all potential confounders, we often rely on a randomized clinical trial setting."
In Celebrex, "To make sure the two samples of patients, example Celebrex and placebo, are comparable with respect to all potential confounders, investigators often rely on a randomized clinical trial setting."
Very similar sentences, correct?
A. Yep.
Q. In valsartan, you say, "Such a clinical study yields a well designed experiment that has the potential for generating reliable prospective data on safety."
In Celebrex, you say, "Such a medical study yields a well designed experiment for generating reliable

prospective data on drug efficacy or safety."
Very similar sentences again, correct?
A. Yep.
Q. And in valsartan, you say, "Such studies were conducted and monitored according to a pre-specified protocol, which details the exposure administered (for example, form, dosage frequency), the clinical or biological endpoints (example, lab value, patient's quality of life, time to remission, time to toxicity event), the study patient population, and other clinical and statistical considerations."
In Celebrex, you say, "Such studies are conducted and monitored according to a pre-specified protocol which details the treatments administered (example, form, dosage, frequency), the clinical or biological endpoints (for example, lab value, patient's quality of life, time to remission, time to a

toxicity event), the study patient population (elderly, suffering from rheumatoid arthritis), and other clinical and statistical considerations."
Those sentences are very similar, correct?
A. No. It's quite different in my opinion, right. I said elderly, something like that.
Do I have that on the left-hand side?
Q. Yeah. You don't think those sentences are very similar, it's almost identical, except for Celebrex you say "elderly and suffering from rheumatoid arthritis."
A. Well, if you want to say similar, that's fine with me. I said a while -- I always aim it at a specific legal case, right. I'm modifying my words -- the words I use before, I'm so glad and still confident that 14 years ago I used it, still applicable today, right. That's a good thing, right?

Staying with a --
Q. It's a good thing for pharmaceutical companies that they have a cookie-cutter report and know what your opinion is going to be before they hire you, correct?
MR. MERRELL: Objection to form. Argumentative.
THE WITNESS: Sir, that's not fair to say -- safe to say.
BY MR. NIGH:
Q. Okay. Let's take a look at the next sentence. "The trial is usually randomized and blinded."
Do you see that?
A. Yep.
Q. And in Celebrex, it says, "The trial is usually randomized and blind."
Very similar sentences, correct?
A. Yep.
Q. Next in valsartan, it says, "Subjects are assigned randomly to one of

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the study arms and neither physicians nor patients are told whether the patient is receiving an active exposure or a control."

In Celebrex, 14 and a half years ago, you put, "Patients are assigned randomly to one of the study arms and neither physicians nor patients are told whether the patient is receiving an active drug, Celebrex, or a placebo."

Very similar sentences, correct?

A. No. To me, they're quite different.

Q. Okay. The wording is almost in the exact same order in both sentences. All you've done is subbed out what's relevant to Celebrex versus valsartan, right?

A. To me it's quite different, isn't it?

Q. Okay. Well, we'll let the jury look at that and decide.

The next sentence says,

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"This avoids selection bias or other experimental bias."

In your other report you say, "This avoids selection bias or other experimental bias."

The exact same sentence, correct?

A. Yep.

Q. Next, you say, "When appropriately designed, results from a well conducted randomized clinical trial are regarded as a gold standard in controlled settings to evaluate the efficacy and safety of an exposure."

In Celebrex, you say, "Results from a well conducted randomized clinical trial are regarded as a gold standard in controlled settings to evaluate the efficacy and safety of a treatment."

Very similar sentences, correct?

A. Yep.

Q. And again, in valsartan, we

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don't have any clinical trials assessing increased risk or whether there's an increased risk with contaminated valsartan, correct?

A. I just point out what is the gold standard for evaluating an exposure. That's what I'm trying to say. I didn't say anything about valsartan case. But yeah, if you read the -- go on and read my next paragraph, you can see it, right.

You can see there's a gold standard. Unfortunately, we cannot do it. As you said very well this morning, we cannot randomize the patient, right.

Q. Right.

MR. NIGH: Looking at -- looking at Page 19, Paragraph 31, and look at Paragraph 14 in Celebrex.

31, please. Those are the references. Paragraph 14. Further up.

BY MR. NIGH:

Q. In valsartan, you start off

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with, "Even if we accept Dr. Madigan's criteria that the false positive rate of .05 is an arbitrary threshold value, this procedure was generally used to establish the so-called statistical significance of a report when testing a single clinical endpoint in a single study."

In Celebrex, you put, "The 95 percent level for the confidence interval or the 5 percent level of significance for testing hypothesis is typically used by investigators and statisticians to establish the statistical significance of a result when testing a single clinical primary endpoint."

Similar ideas quoted in each of these, correct?

A. No, I don't think it's similar. But it is the same principle.

Q. Well, let's look at the next sentence.

You put, "This level can be very liberal."

And on the other side, you put, "This level can be very liberal."
That's identical thus far, right?
A. Yep.
Q. And next in valsartan, you wrote, "I.e., can result in statements of statistical significance when none exists."
In Celebrex, 14 and a half years ago, you put, "I.e., can result in statements of statistical significance when none exist."
Those are identical, correct?
A. I'm glad it's still 14 years after, still valid argument.
Q. And in valsartan, you put, "If multiple statistical tests and/or studies are examined simultaneously."
In Celebrex, you put, "If multiple endpoints are examined simultaneously."
Very similar, correct?

A. Yeah.
Q. Looking next you've got, "When using" -- using --
MR. NIGH: Going down, "Using the 5 percent rule."
BY MR. NIGH:
Q. "Using the 5 percent rule for claiming statistical significance to analyze simultaneously a large number of tests in a study will yield a high rate of false positive findings."
In Celebrex, "Using the 5 percent rule for claiming statistical significance to analyze simultaneously a large number of endpoints in a study will yield a high rate of false positive findings across all endpoints."
Very similar statements, correct?
A. Yep.
Q. Next you put, "Often, the overall false positive rate could be as high as 20 percent or more, that is, a very high chance of finding exposure is

not safe with respect to control, when in fact there is no difference between the two groups."
Your next sentence in Celebrex, "It is not unusual that when the 5 percent test hypothesis rule is applied simultaneously to a number of endpoints in the study, the overall false positive rate is as high as 20 percent, that is, a very high chance of claiming a drug is not safe with respect to placebo when in fact there is no difference between the two groups."
Very similar statements, correct?
A. Okay.
Q. Taking a look at 30 -- so you've made the statement multiple times that you're glad you're consistent between your reports back in, you know, 14 and a half years ago.
Have you been consistent with reports even longer and earlier than that?

A. Well, if you can show me, I'd be happy to read it.
Q. You don't know? Do you -- were you continuing to use these cookie -- a lot of these same cookie-cutter statements in reports that you did before Celebrex 14 and a half years ago?
MR. MERRELL: Objection to form.
THE WITNESS: You're asking me if I did something earlier than Celebrex study? That's what your question, sir?
BY MR. NIGH:
Q. Yes.
A. I don't remember, sir.
Q. Now, you said earlier that you don't hold yourself out to be a toxicologist, correct?
A. Correct.
Q. And so you wouldn't consider yourself to be an expert in toxicology, correct?

A. Correct.
Q. You said earlier that you don't hold yourself out to be an epidemiologist, correct?
A. Correct.
Q. So you wouldn't consider yourself to -- you wouldn't hold yourself out -- or being -- sorry. Strike that.
So you wouldn't consider yourself to be an expert in epidemiology, correct?
A. Correct.
Q. You said earlier that you don't hold yourself out to be a pharmacologist, correct?
A. I remember -- I didn't remember you asking me about it. But the answer is no, I don't think I'm a pharmacologist.
Q. So you wouldn't consider yourself to be an expert in -- my question was pharmacologist. Not oncologist.
You wouldn't consider

yourself to be an expert at pharmacology, correct?
A. That's correct.
Q. Okay. Now, Doctor, you said that you analyzed two valsartan epi studies, even though Dr. Madigan had not looked at any valsartan epidemiology studies, correct?
A. Yes, sir.
Q. What was your purpose for looking at those two valsartan epidemiology studies?
A. Well, you know, when I read Dr. Madigan's report, he used dietary studies, he used occupational study, to infer the safety issue about an impurity in valsartan.
I ask myself right away, how come Dr. Madigan did not use a direct route and to understand the safety issue of impurity in valsartan.
So I believe -- forgive me, I don't know the sequence. Either I ask the lawyers or the lawyer actually

already send the papers to me, which is two studies. One is being called a Danish study, the other one we call the German study.
And I read both. I say, wow, those directly addressed issue about impurity questions, which are more relevant to our question in this legal case, compared with the way Dr. Madigan approach.
That's why I think it's important to point out there were studies available directly addressed your question. Period.
Q. What do you think the purpose of Dr. Madigan's report -- expert report was?
A. The purpose of Dr. Madigan, of course, obviously, he want people to extrapolate the results from dietary studies or occupational study to valsartan case. That's my understanding.
Q. What kind of results was he trying to extrapolate, what were the

results referring to from the dietary studies and the occupational exposure studies?
A. We can go over Dr. Madigan's report, you know, line by line and figure out, okay, what he wants to do.
Q. No. I'll bring up the report if we need to. But I'm asking you, in terms of your knowledge, what kind of -- the purpose or what kind -- strike that. I'll start over.
What kind of results was he trying to extrapolate? What were the results referring to from the dietary studies and the occupational exposure studies?
A. Can we actually go to his report?
Q. This is a big picture question. It's not a line-by-line question.
A. What?
Q. I said this is a big picture question. It's not a line-by-line

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question.
What was the purpose of his report in terms of extrapolating results? What kind of results was he trying to extrapolate?
A. Well, he did many things. I'm not quite sure how I can use one sentence to summarize for you.
I think the best way, if we get both reports and we all can understand what he wants us to understand it, what my comments about it, right. That's fair game.
Instead you're asking me, what do you think about what Dr. Madigan wants us to understand, right.
I mean, let's go through his report. And I'm going to answer you what he wants us to understand.
Q. Are you saying that without looking at the report right now, you can't answer the question as to what the purpose of his report was in terms of extrapolating results from dietary

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studies and occupational exposure studies?
A. Sir, he did so many things, I cannot give you one sentence to summarize what I got from his report.
And if you wanted to know my -- the overall disagreement, you can just go back to my executive summary. Also, my conclusions, right. You can understand exactly what my positions are and what I have concerns about Dr. Madigan's report.
I can read it for you, if you wanted to. I can read my summary, also my conclusion.
Q. I've read your report and your summary and your conclusions many times. Okay. I don't need to read that word for word during this deposition. I've done it many times. I don't need the instruction on what to go to for your opinions.
I'm asking a simple question.

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And the best that you can answer it, what do you think he was trying to extrapolate from the dietary studies and occupational exposure studies?
MR. MERRELL: Objection to form. Asked and answered.
THE WITNESS: I cannot answer you.
BY MR. NIGH:
Q. What was he looking at in the dietary studies and the occupational exposure studies? What sort of figures?
A. If you allow me to go through his report, I can answer you. I cannot answer you without looking at the report, and my report.
Q. As you sit here right now, you can't tell us, you know, what results he was looking at, just in general, or describe them in dietary and occupational exposure studies?
A. Well, sir, listen, why don't you just go to my -- let me use mine.

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You don't have to read it. You said you read my report word by word, okay.
I'm going to read what I wrote, and I'll tell you what he translate from dietary to valsartan case. Is that okay?
Q. Sure.
A. Conclusion. Paragraph 37.
Right. Dr. Madigan claimed that NDMA statistically significantly increased gastric cancer risk arise in LCEs as low as 1,962 ug, is the number. The equivalent threshold for lung cancer so-and-so, for the other cancer, and et cetera, right? Blah, blah, blah, blah.
Based on the report by Dr. Madigan, that's what you try to convince us. He said well, listen, guys, if you have this ratio of so-and-so, you have high risk to get cancer, different cancer. Right.
I'm saying those claims cannot be justified with the issues and the concerns I raise in this report.

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That's 37, okay.
38, the same concerns apply to the claims in Paragraph 34 in Dr. Madigan's report. Dr. Madigan's 34, that's the methods, he want to send to us, right. That's -- answer your question.
So moreover, those essential values may not be transportable in the case of impurity -- I shouldn't use contaminated -- valsartan without appropriate validation, okay.
But he wanted us to believe the findings from dietary study or occupation study can be transported automatically to the valsartan case, right, with those threshold numbers.
That's my understanding, okay.
Q. You understand that at no time in all of Dr. Madigan's report does he ever use the word "threshold values" in describing those values, correct?
A. I don't remember. But I

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quote here "the equivalent threshold for lung cancer" is so-and-so. If I misquoted the word "threshold" I apologize. Right.
Q. Back to my original question. He was looking at -- what is the LCE?
A. The way I understand, lifetime exposure for the contaminant.
Q. And that would be lifetime exposure of what?
A. From NDMA, for example.
Q. And what would the ug refer to?
A. I'm sorry?
Q. What would the ug refer to in his report? What was your understanding of what that refers to?
A. AOGE, you're talking about?
Q. No, ug. You used the words "ug" in your reading you're --
A. Oh, it's a measurement. It's smaller than milligram, mg.
Q. What does -- what does ug

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stand for?
A. I don't remember exactly. I think it's smaller than mg. I don't know what its scale, smaller than mg.
Q. You don't know ug refers to or what he's referring to in this report, when you put ug?
A. I can copy what Dr. Madigan say.
Q. You just copied what Dr. Madigan stated, but you don't know what the ug means?
A. Ug is a scale which measure how much the exposure, right, like a g, mg, like ug. That's a different scale, measure how much contamination in the blood or whatever in your body.
Q. Explain quantitatively what ug means?
A. I don't remember how to define, sir.
Q. Do you know what ng means?
A. Mg?
Q. N. N as in Nancy. Ng, do

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you know what ng means?
A. I don't know.
Q. Okay. Do you know what mcg would refer to?
A. No. I'm not a toxicologist. I don't know the scale.
Q. So when you see him put 4,000 -- or just -- sorry, the first one that you have quoted in Number 37, "Dr. Madigan claimed that for NDMA" -- actually let's do this. Let's put this up on the screen.
MR. NIGH: LP -- so the jury can see it too -- LP-1557.
This was previously marked Exhibit 3.
And turn to number -- Paragraph 37. And let's blow that up.
BY MR. NIGH:
Q. This is in your report.
MR. NIGH: Blow up Paragraph 37.

BY MR. NIGH:
Q. So in your report you put in Paragraph Number 33 in the report, "Dr. Madigan claimed that for NDMA statistically significant increased gastric cancer risk at LCEs as low as 1,962 ug."
What does that refer to quantitatively, 1,962 ug?
A. I am not a toxicologist. I cannot answer you how much is that exposure.
Q. That doesn't take a toxicology opinion to know what ug means, right?
A. I don't know, sir.
Q. So you don't know what Dr. Madigan was referring to when he put the word ug or the letters ug, and you couldn't tell this jury quantitatively what he's referring to when he says 1,962 ug, right?
A. I don't know how much he's mentioning to quantify this.

Q. Do you know how he calculated these LCEs, what formula?
A. Well, he calculate -- sorry. Sorry, sir. Say it again.
Q. Do you know how he calculated these LCEs or what formula he used?
A. Oh, yeah, yeah, I know mathematic formula. So what he did is following: He compared this Q1 to quarter -- the lower dose, that exposure against the Q4, which is the highest dose.
Sometimes he use five set instead of four. And then he compared the Q1 against the Q4. Then if he says it's statistically significant, then I'm going to take this study, the exposure level, whichever he described, that's Study Number 1, right.
Then we go to another study. If it's not a statistically significant, he dropped it.
Then he go to the third

study. If he find a statistical significant, he count -- he take the highest, the Q4, the level, right, for the lifetime exposure, which I don't know how much to quantify. That's what he explains.
And then he added up, take an average. That's my understanding, he calculated the so-called lifetime threshold value.
Q. Have you ever calculated lifetime cumulative exposures in any of the work that you've done?
A. No.
Q. So this is -- this is novel to you, when you see these calculations of lifetime cumulative exposures, correct?
A. Novel in a way. Is not a statistical novelty because statistical is very straightforward. That's what I'm concerning about his statistical argument and the claim.
I cannot interpret the

physical meaning of this exposure, the level we're talking about.
Q. I'm not sure you understood what he was doing, because you just mentioned that if he found that it wasn't statistically significant, he would drop it.
Why do you think that?
A. Well, that's my understanding. If I misunderstood what he did, I apologize.
Q. He has Table 1, and he's calculated LCEs for nearly every single dietary study. Did you realize that?
A. Hold on a second. Let me see the Table 1 here. Okay.
MR. NIGH: Yeah. Let's go ahead and show it. LP-1558.
Table 1.
BY MR. NIGH:
Q. It's important if you're going to criticize an expert's opinion, that you understand what they're doing, correct?

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A. Oh, absolutely.
Q. Okay. Looking at Table 1, do you see here how he calculated LCE for nearly every single dietary study?
A. Yeah, he lists the LCE and every study they have -- well, some is missing. But okay, yes.
Q. Nearly every one. He doesn't have one for Knekt.
Do you see that?
A. Yeah.
Q. Do you know why he wouldn't have one for Knekt?
A. No, sir.
Q. Do you know if Knekt gave the value of NDMA in the fourth quartile?
A. I'm sorry, sir. I don't understand your question.
Q. Now, looking at this, can you explain -- let's just take a look at Palli. And you see under LCE, it shows 5,260?
Do you see that?
A. Yes, sir.

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Q. And that's one -- that's SS. What do you think SS stood for?
A. The effect size, you're talking about.
Q. You think SS on his chart stood for sample size?
A. You mean the last two -- the column statistical significance? Is that what you're talking about? Or which one are you talking about?
Q. SS?
MR. NIGH: Can we highlight that column.
BY MR. NIGH:
Q. What do you believe that stood for, that SS?
A. I don't know, the SS means.
Q. Okay. Did you happen to pull these dietary studies to where you could figure out what the SS meant in his table?
A. No, sir.
Q. What do you think effect size meant?

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A. Effect size, if I interpret it correctly, that's the one we are talking about in the morning, about for example the difference between the two, you can use the hazard ratio, you can use odds ratio, you can use risk ratio, et cetera.
Q. Right. Odds ratio, risk ratio and HRs, are are all commonly referred to as effect, or effect size, correct?
A. Yes, sir.
Q. Okay. But you don't know what the SS, right next to that stands for in the table?
A. I -- I don't know. I better not make a guess. But I think I know what is going on. But I apologize. I don't want to say -- I'm not 100 percent sure. I don't want to say anything.
Q. Well, you're commenting on his report. That's what you were hired to do, correct?
A. Yes, sir.

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Q. So I'm asking you, what do you think his report, the SS stood for?
A. I don't know.
Q. Okay. Next, do you remember you asked about country, that second column on this table. You raised country. Doesn't he provide the countries here?
A. Provide country to me? Sorry.
Q. For each study. Doesn't he provide the countries for each study?
A. In the table, yes.
Q. Right.
A. Yes, in the table.
Q. And design, what do you think the CC or the C stands for?
A. Sorry. Where is the CC? I'm sorry.
Q. Right underneath "Design." Do you see CC and C?
A. Oh, I have no idea what CC means.
Q. So as you reviewed his

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expert report and this table, you didn't know what CC stood for or what C stood for?
A. Yeah, because that's not relevant for statistical analysis.
Q. The type of study or the design of the study can be relevant, right?
A. Well, I don't know, what kind of observational study or what, because basically, he didn't tell us exactly what's going on in the report. Right. Did he say anything about CC here. In the footnote, did he indicate CC?
Q. Did you pull the studies to see what CC or C may refer to?
A. No, because I am basically using his report. Anything he send to me, I would read it very carefully. But if he skip it, I said well, that's your problem. It's not my problem.
Q. But you don't understand what he's referring to. And commenting

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on his report, if you don't understand it, isn't that your problem?
A. I don't think so. Because he's got very important statistical analysis, he would have put a footnote underneath the table. Say what do you mean by CC, what do you mean by SS.
Q. Why do you think -- what makes you think he's required to do that?
A. Otherwise, how in the world the people outside the field understand what he's talking about.
Q. Show studies. Just pull up the studies, right.
A. All right. How in the world would you --
Q. Just pull up the studies to see what it stands for.
A. You talk over me. If that -- if you want to talk, I'll let you talk first.
I just want to share with you, you're asking me how come I don't ask Dr. Madigan what CC means. I say

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well, listen, he didn't even list it, right. He didn't explain to me in the report.
And I was told my assignment is to look at the report. I don't have to question about Dr. Madigan did. I say well, listen, if you give me the information, I use it. If you don't give me information, I don't use it.
Q. Well, he gives you the information because he cites to every one of these studies. So you can simply --
A. But what --
Q. Hold on. I was asking the question that time.
A. Yeah.
Q. So you can pull up the study to see what the design of that study is and figure out what his CCs and Cs are referring to on this chart, right?
A. Nope. I can't.
Q. You don't think you can?
A. Sorry?
Q. You don't think you can do

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that?
A. He should have for us. Why should we go into each study to check what he mean by CC, what is a single C, what is a double C?
Q. Okay. So you don't have any criticism in terms of the designs of these studies or how we look at design of study in terms of extrapolating these results?
A. I don't have information about his abbreviation. Say -- this study he gave a double C, the other one is a single C.
But for most of studies, I go into the study to understand what kind of observational study they conducted. Is it prospective or actually retrospective? Is it cohort study or meta-analysis?
That's what I did. I don't have to go in to ask Dr. Madigan what he's talking about, what is a CC, or what does a C means.

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Q. Okay. Next column, base high dose ug.
What does that refer to?
A. That's, my understanding Q4, whatever you want, base on high value.
Q. Okay. Your understanding is that would be the highest quartile?
A. Well, sometimes use different topic, right, not only the quartile, something else.
Q. Okay. How about average -- approximate average age. What does that refer to?
A. That's probably obvious, right. That's -- everybody understands average age. That's the study population, I believe.
Q. You believe that's the average age in the study?
A. Of the subjects.
Q. Okay. Explain that to me more. You believe that's the average of all the subjects in the study?
A. Well, I better check the

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papers. And I can confirm you the 60 is exposure time of the age of exposure, or the age of the subject, right, in the study, right.
Q. Okay. But as you sit here right now, looking at this table from his chart, you couldn't tell me one way or the other?
A. Yeah. I need to double-check.
Q. Okay. Looking at LCE ug, what does that mean?
A. Well, as I explained before, he took large -- the highest dose, right tried to figure out the actual level, LCE. That's how he figure out lifetime exposure.
Q. Okay. So explain to me what you think his formula was in looking at this table to come to 5,260 for Palli, LCE?
A. Well, this is -- my understanding is he just copied from the paper. He didn't do himself. He doesn't

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have the data. He doesn't have the data for patient, right.
Q. You think he copied the 5,260 LCE from the Palli study?
A. I believe that's my understanding.
Q. Do you think that all of these numbers under LCE --
MR. NIGH: Let's highlight all of those in yellow, all the way down.
THE WITNESS: Well, that's what my understanding.
Otherwise, he should explain to us how they calculate this number, right.
With the individual patient levels he calculated number, or actually is it from the papers, right.
He didn't explain too well. He just give us a formula. Say, well, that's calculated lifetime exposure.

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We said, do you have individuals patient level? Obviously, he didn't have it. Right.
So those patients falling into the Q4, for example, right, he did not have those -- everybody's exposure level, right.
Okay. So I doubt he can actually calculate this number using individual patient level.
BY MR. NIGH:
Q. So is it your testimony that you believe these numbers under LCE are lifted from the papers?
A. I believe he find out from the papers. Otherwise I'm not quite sure how he calculated those numbers.
Q. But as you sit here right now, looking at this table, which is a table in Dr. Madigan's report -- it takes up the full page in his report -- you don't know whether or not those LCE values were lifted directly from the

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studies?
A. You're asking me if those numbers are from the papers, right? That's what you are asking, right?
Q. My question was, as you sit here right now, looking at this table, which is a table in Dr. Madigan's report, it takes up the full page in his report. You don't know whether or not those LCE values were lifted directly from the studies, correct?
A. I'm saying he cannot calculate this number using individual patient-level exposure.
Q. So do you know if they were lifted directly from the studies or not?
A. It must be somewhere. Summary statistics from the paper. Otherwise I don't know how he calculate it.
MR. NIGH: Okay. Let's go ahead and take this down.
BY MR. NIGH:
Q. Okay. Back to my questions

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earlier on -- Dr. Madigan's purpose was to look at the cumulative exposure to NDMA that led to increased risk of cancers, correct?
A. Yes, sir.
Q. Now, the two valsartan studies that you looked at, they don't discuss how much exposure that the patients had to NDMA? They don't quantify exposure to NDMA in Pottegard or Gomm, the amount of exposure to NDMA, correct?
A. I have to read the paper again. But my recollection, they did not give a specific individual patient exposure level. But again -- sorry.
Q. So --
A. But again, I needed --
Q. Go ahead.
A. Go back and read -- I'm sorry.
I had to go back to read the paper.
Q. So if Pottegard and Gomm

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don't contain the amount of NDMA that those patients -- that the patients were exposed to in those studies, that would not be useful to Madigan if his sole purpose was to try to look at how much NDMA it would take to lead to increased risk of cancer, correct?
A. Well, again, sir, I don't know in those two papers they have individual exposure value or not. I don't know. I have to read again.
Q. I started out with the assumption that if Pottegard and Gomm do not contain the amounts of NDMA that the patients are exposed to -- so starting with that hypothetical.
Follow me?
A. Sir, I not answer a hypothetical question. I like to see the fact.
Q. I'm allowed to ask you questions as an expert that you take the assumptions, okay.
So my first part that I want

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you to assume that both Pottegard and Gomm do not contain the amounts of NDMA that its patients or subjects were exposed to.
Do you follow me so far?
A. Yes, sir.
Q. If they do not contain the amount of NDMA that they are exposed to, then that would not be useful to Dr. Madigan's question of how much NDMA over a lifetime does it take to get increased risk of cancer, correct?
MR. MERRELL: Objection to form.
THE WITNESS: I'm not a toxicologist, sir. I cannot answer this question. I have no opinion on this.
BY MR. NIGH:
Q. This isn't a toxicology opinion.
The question is, you're reviewing and you're responding to Dr. Madigan's report. If those two

valsartan epi studies do not contain the amount of NDMA that the subjects are exposed to, then that would not be useful to Dr. Madigan's question of how much NDMA over a lifetime does it take to get increased risk of cancer, correct?

MR. MERRELL: Objection to form.

THE WITNESS: I don't answer hypothetical question, even though you have every right to ask me, sir.

BY MR. NIGH:

Q. Are you refusing to answer the question, in terms of assume Pottegard and Gomm do not show how much NDMA its subjects are exposed to?

A. I told you, sir, I have no opinion on this.

Q. Okay. I'm going to ask this again.

Assume that Pottegard and Gomm do not show or discuss the amount of NDMA that its subjects are exposed to.

If that's true, then those studies would not be useful for Dr. Madigan in calculating a cumulative amount of exposure to NDMA that it takes to reach increased risk of cancer, correct?

MR. MERRELL: Objection to form. Asked and answered.

THE WITNESS: I have no opinion, sir.

BY MR. NIGH:

Q. Do you have no opinion because you believe that takes a toxicology mindset to be able to answer that question?

A. Probably.

Q. You believe that in order to calculate a total amount of NDMA, that it would be unuseful to try to use a study that doesn't give you amounts of NDMA. Is that your testimony?

A. Yeah, sir, the problem that I am having here, is that before you even talk about the lifetime exposure, pose the argument without this lifetime

exposure for individual level, we have trouble. We have a concerns about Dr. Madigan's analysis, right.

You cannot even pass the hurdle and say this exposed, this unexposed. Do you have any causality or association interpretation?

We couldn't even go through that piece from the dietary studies or occupational study. How in the world you can go down the next level and claim there was a threshold value, and beyond that we have a concern for cancer risk?

So that's -- I said it very clearly in my report. We couldn't even go through the first hurdle to convince us there was issue, even exposure to unexposed impurity of valsartan. Right.

Then how we can actually go to next level? That's my basic question to Dr. Madigan, and also to you.

Q. My question, if you understand his report, because the word "threshold" doesn't show up anywhere in

his report, right?

A. I apologize if I use the word "threshold." That's the number that he used claiming, you know, beyond this number we are in trouble, right. That's my understanding, that's the common language, right?

If I use the word "threshold" improperly, I apologize. But to me that's the same language we use all the time to say what's the cutoff point, what's cutoff value. We call that a threshold value.

Q. He actually doesn't use the word "cutoff" either.

A. Okay. That's fair. Which language does he use then, sir?

Q. Do you understand that he's not explaining a cutoff, a threshold, line in the sand, none of those. He doesn't use any of that language, right?

A. Okay. Yeah, so he may -- if the level -- if the patient's exposure level, beyond that number he quoted, that

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means this guy have increased cancer risk. Is that correct? That's what he claimed, correct?

Q. Do you see that claim anywhere?

A. Yeah, I mean, that's what he is talking about in conclusion.

Q. Okay. Now, you talked about causality.

As you read his report, did you see a causation opinion that NDMA causes cancer or that valsartan causes cancer?

A. Well, sir, unfortunately he said also very well in the deposition, he was not in the position to talk about causality at all. The most he can do is talking about association.

Even association, we have some question about it, right. And from association to causality, none of those arguments can be -- hold true, right. In some sense we have no idea how to interpret the causality now, right.

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Q. Is it your testimony that there is no association between NDMA and cancer in humans?

A. Sir, I am not in a position to tell you either way. I'm just responding to my lawyers. My assignment is asked very simple, do you think Dr. Madigan's argument in his report is valid? Okay. I'm saying his argument has a lot of holes, and I don't agree with his argument.

I didn't say either way it was association, not association.

My point is that at this point, we don't have much evidence to claim either way. Because most observational study, everybody has limitation, okay.

So I'm not in the position to tell you, sir, there's no association, there is association. I just say we don't have enough data to tell us either way for valsartan case, not dietary, but for valsartan case.

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Q. My question to you is, is it your testimony that there isn't enough evidence to establish an association between NDMA and cancers in humans?

MR. MERRELL: Objection to form.

THE WITNESS: Correct. I said there is not much evidence to say there is association or there is no association. That's my position right now.

BY MR. NIGH:

Q. Now, you included Pottegard and Gomm and looked at those studies.

Was that for you to form an opinion on whether or not there's an association between valsartan -- contaminated valsartan use and cancer?

A. Well, let me say this, sir.

I think the two studies are pretty relevant to address the issue regarding the impurity in valsartan. Okay. It's very direct and to the point. But everybody understands any observation

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study has a limitation.

Those two studies had a limitation, right.

So at this point, I said, well, if I have a choice to look at information about a valsartan impurity, I would have put a more emphasis on these two studies, instead of using a detour method using dietary studies, occupational study to tell me there is some issue about a valsartan impurity.

So that's my position.

I'm not in the position to say, yes, these two studies told us there was no association about the cancer risk and the impurity of the valsartan. And I'm not in a position to say that either.

Q. Dr. Madigan was looking at cumulative exposure and potential increased risk from cumulative exposures to NDMA.

How would you use Pottegard or Gomm to assess cumulative exposures?

A. Well, sir, you asked me the

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same question before. You said if they didn't have -- under the hypothetical, the assumption, there were no individual exposure level using -- Dr. Madigan cannot use their study or data to calculate a so-called lifetime exposure.

I said I'm not in a position to answer your question, because I would really like to review that paper carefully before I answer yours, right.

Q. Well, there's not even -- not just NDMA. But there's not even enough data in terms of amount of valsartan usage in Pottegard or Gomm to try to draw any conclusions in the amount of cumulative valsartan usage that it would take to reach certain increased risk in Pottegard or Gomm, correct?

A. Well, again, sir, forgive me, I needed to read the paper carefully again, because I've been -- I've not read any their papers about -- after I submitted the August 2nd report.

Q. So as you sit here right

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now, you can't answer whether or not there was enough information in Pottegard or Gomm to draw any conclusions in the amount of cumulative valsartan usage that it would take to reach certain increased risk in those studies, correct?

A. I don't recall, sir.

Q. Now, you included valsartan epi to see whether these valsartan epi studies, Pottegard and Gomm, demonstrate the contaminated valsartan had an association or not with cancer, correct?

A. Yes. We just simply stated what -- the conclusion from the papers, right. They didn't find association between those two.

Q. Now, there are other -- you understand that there are other drugs that are -- also have been shown to have NDMA, correct?

A. Well, I vaguely know a little bit. Not much.

Q. Well, do you know that losartan and irbesartan have been

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demonstrated to have nitrosamines inside of them?

A. I don't know, sir.

Q. Have you reviewed any literature or epi studies to see whether or not there was an association between the nitrosamines in losartan or irbesartan and increased cancer risk?

A. Well, if the reference are not in Dr. Madigan's report, I don't think I read it, except for those few papers that I provide in my report. Otherwise -- not an appendix -- Exhibit A or B, if it's not in this, I didn't read it.

Q. Right. Why wouldn't you have looked at whether nor not other drugs that are contaminated with nitrosamines had increased risk?

A. It was not in my assignment, sir.

Q. But you looked at Pottegard and Gomm, even though that wasn't cited by Dr. Madigan, correct?

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A. Well, you know, this is what I said to you. I'm really curious how come Dr. Madigan didn't use a direct approach to actually use the valsartan impurity study, right, to answer this issue.

So I Googled. And it turns out there were two, only two, that the lawyers send to me, and I couldn't find other studies available right now directly address the issue.

So I thought, wow, gee, this is interesting, how come Dr. Madigan did not cite those two papers, right. To me, that's all relevant to this particular issue, the legal case.

Q. Well, you realize that it's because they don't have any sort of dosing to answer the question that he was asked, right? No NDMA, no amount of cumulative valsartan, right?

MR. MERRELL: Objection to form.

THE WITNESS: Well, if I

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were him, I would have mentioned the papers about -- then you said limitation of the two studies, right. Instead he just totally ignored and didn't even mention anything in his report.
BY MR. NIGH:
Q. You realize there's four other plaintiffs in this -- four other plaintiff experts in this litigation, and all the other four looked at valsartan epi. But Madigan was only asked to look at dose, right, you saw that from his -- from his -- the question that he was asked, right?
A. Oh, no, sir. No, no, no, no, sir. If you read Dr. Madigan's report, first that he established this so-called Q1 against Q4. And he cited all the papers using the dosing-response relationship. That's the first thing he established.
You read this morning about the lung cancer and other cancers, right.

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That's what he did, first place.
Then he go in to figure out this lifetime exposure level, right.
So we have two pieces. The first piece, I have a serious concern about his conclusion. If you cannot sort out exposure, any exposure or a Q4, like for example had some issues, how can we actually go down the next level to figure out what's the value your concerning go about, right.
Q. Okay. So your questioning is -- you know, your response to that is he was also evaluating the strength of association first?
A. Yeah. All the odds ratio he's talking about -- he's compare the Q1 against Q4 or Q -- whatever he used, quintile or quartile, whatever it is, right, lowest against the highest dose, whether there is statistical significance or not. That's first step that he established.
Q. Okay. Turning back to --

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you realize there are other drugs that have also been demonstrated to be contaminated with NDMA, correct?
A. I don't know, sir.
Q. Are you aware that Zantac, generic form name ranitidine, has been demonstrated to be contaminated or have NDMA?
A. I vaguely remember because I was contacted by lawyers on the Zantac. They actually -- I believe, either I Googled or they send me some kind of documents.
By the way, I was is not retained for that case at all.
In any event, I notice Zantac has impurity also.
Q. It's NDMA for Zantac, correct?
A. Correct.
Q. And also metformin, some metformin drugs have been contaminated or have NDMA, correct?
A. That, I don't know.

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Q. Did you review any epidemiological studies for ranitidine a/k/a Zantac, or metformin to see whether they had increased risk of cancers?
A. No, sir.
Q. Why not?
A. Well, first, I was not retained by the Zantac team, the legal team, so I don't think I have the time to even begin to understand the impurity of other medicine.
Q. Well, you looked at studies related to whether or not the NDMA in valsartan, whether or not valsartan showed increased risk of cancer. Why wouldn't you look at other drugs that also have NDMA and see if there's an increased risk of cancer?
A. Well, because Dr. Madigan didn't even mention about other medicines, sir.
My job is mainly to address an issue in Dr. Madigan's report.
Q. Dr. Madigan didn't look at

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Pottegard or Gomm either, right?
A. Yeah. I don't know why. And he didn't mention anything about Zantac, metformin. I didn't see from his report, unless I missed something.
Q. Did you think it wasn't important to consider the other drugs or other medications that had NDMA in thinking about whether or not NDMA in valsartan could cause increased risk?
A. Well, that's a very interesting question. You should ask Dr. Madigan how come he didn't include it in his report, if you think such an important issue. If you can actually utilize to tally the evidence across all the medicines, how come he didn't use it?
Q. Well, I'm asking you right now.
Dr. Madigan --
A. Well --
Q. He didn't include Pottegard or Gomm either.
A. Yeah.

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Q. So I'm asking you.
A. Yeah, that's right.
Q. You included Pottegard and Gomm.
A. Yeah.
Q. This question isn't for Madigan. This isn't in relation to Madigan. Let's throw Madigan out the window right now. My question is to you. You included Pottegard and Gomm?
A. Yeah.
Q. Okay. So you included those two studies. Why else -- why didn't you include the other studies that showed NDMA in medications?
A. Sir, is this a case for the valsartan impurity or is this a case for Zantac impurity or metformin impurity questions?
Is that -- I have to worry about other medicine contamination to answer your valsartan question?
You know, I have a problem even to understand, you use a dietary

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study, extrapolate a result to valsartan. I said, you actually can use the metformin result to this valsartan case? The population is so different. The patient population is so different, right.
The Zantac population is quite different than the valsartan population.
So you are rounding a circle here. You say, well, how in the world I can use other treatment, other drug contamination to help me? I said, well, there's two studies. Danish and German study directly address this issue.
Why should I ignore? Why should I even bother to worry about other drug contamination issue for this case.
Q. Okay. That's helpful. I think you're saying that you didn't look at metformin or Zantac because they have different populations than the valsartan population, correct?
A. Yeah. Sir, I don't even

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know metformin had an issue. I know vaguely about Zantac issue.
Q. Okay.
A. Even that part I just vaguely know a little bit. I am not for sure how much research I have to be doing to answer your current question about valsartan impurity, right.
Q. Right. So when you're thinking about an impurity of NDMA in valsartan, you felt like you didn't need to look at Zantac or Metformin, because they had different populations. They also have a different mechanism as to how NDMA is formed. Did you know that?
A. No, I don't.
Q. Zantac breaks down -- it's been stated that Zantac breaks down not a manufacturing defect. So it's not in the drug right off the assembly line.
Zantac breaks down due to heat, humidity, time, possibly other factors inside of the body.
That's what's been stated,

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right?
MR. MERRELL: Objection to form.
THE WITNESS: Sir, I'm sorry. Go ahead. I'm sorry, I don't mean to cut you off, I'm sorry.
BY MR. NIGH:
Q. Do you recall seeing that, that the way in which Zantac gets NDMA, is much different than the way in which valsartan has NDMA, correct?
A. No, sir. I'm so glad you learn so much in the past few months, right. And I have no idea what is the underlying process of this contamination works, right, for each medicine.
I really admire you for you to learn things so fast, right.
Q. But if you were wanting to think about whether or not to consider Zantac epidemiological studies as to whether or not that's beneficial for valsartan epidemiology and the question

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at hand here, you would want to know that the way in which they're getting NDMA is similar, correct?
A. I have no opinion, sir. I am not a toxicologist. Besides, I have not reviewed the papers in detail regarding the Zantac impurity question.
I'm not quite sure where -- where the question right now, sir. You continue asking me the question about other impurity, right, other drugs, which was not in my assignment, which is not my expertise.
I'm not quite sure how I can actually help you on this case to figure out that the valsartan -- we haven't solved the valsartan issue again. Why we actually worried about other contaminants, right.
Q. Would you also, in understanding the question between Zantac and the amount of NDMA versus valsartan and the amount of NDMA, that the amount of NDMA that's been reported in Zantac,

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is much different than the amount of NDMA that's been reported in valsartan. That's something that you would also want to consider as you're thinking about whether or not you look at Zantac epi studies for the question at hand here, right?
A. No. I don't think it's relevant. It was not in my assignment.
Q. You don't think that it would be relevant -- when you're questioning whether or not to include -- you didn't look at Zantac studies, right, Zantac epi studies?
A. Sir, my assignment was not regarding the Zantac. My assignment is regarding the impurity in valsartan, right.
Q. Right.
A. So I don't know that you can transport the findings from Zantac to our current case or not. I have no idea, sir. I cannot say either way, right. I'm not an epidemiologist. I am not a

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toxicologist. I cannot answer your question.
If you can educate me here, I'm happy to learn from you, right.
Q. Nonetheless, you looked at Madigan's report, and in thinking about whether or not there's an association between valsartan that's contaminated with NDMA and increased cancer risk, you decided to look at Pottegard and Gomm, not any of the Zantac epi studies, correct?
A. The Danish study, German studies are relevant to our current case.
Other medicine contamination may be interesting, but it was not in my assignment.
Q. What do you mean by it wasn't in your assignment?
A. Well, sir, if you read in my Section C, very clearly you helped me this morning even read with me my assignment, right. Does my assignment say anything about I should worry about

Zantac impurity? Does it say anything?
Q. Let's take a look. Number 11. We're going to pull up your expert report. I want to be real clear here.
MR. NIGH: Number 11, Page 5. Put that on the screen.
Let's blow that up again.
BY MR. NIGH:
Q. It says, "I have been retained by defendants to provide an expert opinion in the litigation styled" -- and chose valsartan. "Specifically, I was asked by counsel for defendants to review and assess the opinions presented by David Madigan, who submitted an expert report on behalf of the plaintiffs analyzing the results from the dietary and occupational exposure studies to infer potential risk of carcinogenicity from NDME or NDEA impurities in valsartan and to provide my own assessment of those issues."
That's what it says, correct?

A. Yes, sir.
Q. Okay. Now, that assignment says "analyzing the results from the dietary and occupational exposure studies to infer potential risk of carcinogenicity of NDME or NDEA impurities in valsartan." That's the first part of that statement. That statement doesn't include Pottegard or Gomm, correct?
A. Correct.
Q. The second part says, "And to provide my own assessment of those issues."
Is it that part of the assignment that you felt authorized to look at Gomm and Pottegard?
A. I said in my report very clearly after I raised some concerns about Dr. Madigan's report, I said, well why don't we actually directly address the issue using the valsartan impurity studies, right, instead of you go to the bypass, somehow take a detour, right,

using other studies. So that's what I'm try to. I provide to you two studies directly addressed issue here, right.
Q. I understand.
A. That's what I'm doing, yeah.
Q. You made the determination in your understanding in providing an assessment of those issues, to go to the valsartan epi studies Pottegard and Gomm, right?
A. Yes.
Q. Why didn't you make the determination to then also look at other medications that were contaminated by NDMA?
A. I am not for sure I should do it that way, sir.
If I have unlimited time in my life, I wish I can learn a lot of things from you guys. You know, you guys catch things so quickly. I don't catch things very quickly. I need a lot of time to understand the toxicology report, even epidemiology report.

Honestly, I have a day job. I cannot afford it, right, to do something is irrelevant to this case.
Q. Okay. The last part of your sentence, you said, "Honestly I have a day job, I cannot afford it to do something irrelevant to this case."
Did you believe that that would be looking at the other medications that were contaminated by NDMA, those epidemiology studies, looking at those studies, would be something that is irrelevant to this case?
MR. MERRELL: Objection to form. Calls for a legal conclusion.
THE WITNESS: Well, I apologize, sir.
You know, if you think that this is very important, looking at other medicine impurity, I wonder how come your expert witness didn't even take a look at it, right.

If they take a look at it, I'd be happy to make a comment about their findings. But they didn't do anything. They didn't even bother to go to valsartan study.

I actually made a little bit of effort to bring up to you guys to say, well, two studies directly addressing issue.

You said, wow, that's very good. Why don't you go the next mile and figure out what other things like Zantac, Metformin.

I said, well, gee, you know, sir, how many contaminated drug in the world, how many drug I should worry about before I submit my report.

Sir, this is unrealistic now, right. It is really not relevant anymore.

BY MR. NIGH:

Q. Now, in your answer, I hope

you understand that there -- we have more experts than just Dr. Madigan, right?

A. I don't know, sir. I don't know how many experts you have.

Q. So you haven't seen the opinions, you haven't seen the reports of Dr. Etminan, Dr. Panigrahy, Dr. Lagana, or Dr. Hecht, correct?

A. The only report I read very quickly, not very detailed, was the epidemiologist that you mentioned, right. Other than that, I didn't read the -- your expert witness report.

Q. Dr. Etminan you reviewed very quickly. Is that what you just said?

A. Yes. I did glance over. Because I find out, interesting enough, all his study he recommended Dr. Madigan included. I said well, gee, you know, in that case I don't have to read the epidemiology expert witness, because Dr. Madigan solely depend on the epidemiology. Your other expert read the

guidance, right, to say, wow, Dr. Madigan, you should read X, Y, Z.

So Dr. Madigan say, oh, yeah, yeah I take it. So in his deposition Dr. Madigan said, Yes, I only consider those documents or papers provided by the epidemiologist. That's my understanding.

Q. So as you quickly reviewed Dr. Etminan's report, you believe that he doesn't have Pottegard -- Gomm or Pottegard in his expert report as far as you understand?

A. No, sir, I apologize, I don't remember exactly the report anymore. I'd be happy to read it and get back to you.

Q. But as you sit here today, you wouldn't be able to say one way or the other, right?

A. Correct.

Q. And also you wouldn't be able to say one way or the other whether or not Dr. Etminan, plaintiffs'

epidemiologist expert, whether or not he's included review of ranitidine epidemiological studies, correct?

A. Correct.

MR. MERRELL: Counsel, we've been going about an hour and a half. Can we take a break shortly?

MR. NIGH: Yeah, can you give me just about two more minutes and I think it will be a good time for a break.

MR. MERRELL: Of course.

BY MR. NIGH:

Q. So I want to see if I understand this correctly.

You found it relevant, in terms of the questions here, to look at Gomm and Pottegard, but you did not find it to be relevant or close to the issues at hand, I think you used the word "irrelevant," that is, not a legal conclusion, but you used that word.

You found it to be

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irrelevant to look at ranitidine or Zantac epidemiology or Metformin epidemiology studies, correct?
A. I apologize to use the word "irrelevant." That's probably the wrong word to use it.
I'm trying to say is my assignment did not include taking a look at other contaminants, right, in other medicines. That's my first answer to you.
Second, honestly, I don't have so much time on hand to deal with all other medicines. I have no idea how much other medicine is contaminated, I have no idea. If you ask me, how come you don't do Zantac, Metformin, somebody else would say how come you don't do A, B, C, other drugs. That is the answer, sir.
MR. NIGH: Okay. I think we can take a break now. Thank you.
THE VIDEOGRAPHER: The time right now is 2:51 p.m. We are off

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the record.
(Short break.)
THE VIDEOGRAPHER: The time right now is 3:12 p.m. We're back on the record.
BY MR. NIGH:
Q. Doctor, I want to ask you about the levels of NDMA that were found in valsartan, okay?
A. Yes, sir.
Q. Do you know what the levels of NDMA were that were found in valsartan?
A. I don't know, sir.
Q. Do you have any way of describing the levels of NDMA that were found in valsartan?
A. No, sir.
Q. Do you have any idea or any way of describing how long the valsartan medications were contaminated for in the U.S.?
A. No, sir.
Q. So you haven't seen any

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internal testing or any FDA testing that describes the amount of NDMA that was found in the valsartan drugs, correct?
A. The only information I got is like you said for mainly from Dr. Madigan's report.
Q. Okay. Well, what do you know in terms of internal testing or FDA testing of the amount of NDMA that's in the valsartan drugs?
A. No, sir.
Q. You have no knowledge of that, correct?
A. No, sir.
Q. Okay. And how about the amount of NDMA that was measured in people's diets and the dietary levels?
A. I have no idea, sir.
Q. So as you sit here, you can't make any statement or comparison of the amount of NDMA that was in people's diets and the dietary studies versus the amount of NDMA found in the valsartan pills, correct?

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A. Well, I know a little bit about a dietary, the food and recall. You know, for example, someone can ask me, last month, what did you eat, how many strip of bacon you eat, right, something like that. And they extrapolate those kind of things and convert it to the level of exposure. That is only the level I understand, sir.
Q. Do you know how many -- how much NDMA that they were reporting in their daily diet in the various quartiles in dietary studies?
A. Well, this quartile, some paper they describe the level. So I know the level, but I can't understand biologically how much you are talking about, right, in your body or your bloodstream, whatever you define.
Q. Do you know how much NDMA that they were saying was in the foods in those dietary studies, do you have any way of describing that?
A. No.

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Q. So if I were to make the statement that the amount of NDMA found in valsartan pills was as high as 600 times the amount of NDMA in a person's daily diet, you would have no way of knowing if that was true or not, correct?

MR. MERRELL: Objection to form.

THE WITNESS: Yeah, I have no -- I don't know where I can get that information from Dr. Madigan's report.

BY MR. NIGH:

Q. Is that something you looked for in Dr. Madigan's report and you just didn't find it or you don't recall looking for that?

A. Well, he maybe mention something. Maybe if I can read his report again I can confirm. What I think is he did not mention or I forgot what he mentioned. Maybe somewhere he mentions well, valsartan impurity probably is X times higher than whatever is, right.

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That's probably what he said somewhere. But I need to go back to his report.

Q. But as you sit here right now, you don't remember any comparison that Madigan made or that you've seen in terms of comparing the amount of NDMA in the valsartan drugs versus the amount of NDMA in these dietary studies, correct?

A. I don't recall, sir.

Q. And as you looked at the dietary studies, you don't recall whether or not, when dietary studies had lower amounts of NDMA in the highest quartiles, they were less likely to show effects than when they had higher amounts of NDMA in the quartiles, the highest quartile. Do you recall ever looking at that?

A. The analysis Dr. Madigan did most is sort of transport from publication. For example, in a publication, the majority of publications, they compared the quartile, right, the Q1 against the Q2, Q3, and Q4. And most they are reporting on the trend

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test combining those three tests altogether. That's what Dr. Madigan mainly depend on, right, using those P-values, using this statistical significance job and word, to claim there is issue from this study for this cancer.

That's what I'm concerned, from a statistical point of view, is this a valid way to evaluate the safety of an impurity in valsartan.

Q. You don't recall looking at dietary studies or even Madigan's report, to see whether or not as dietary levels are lower -- sorry. Strike that.

You don't recall looking at dietary studies or even Madigan's report to assess whether or not if the dietary levels are lower in the highest quartile in various dietary studies, then it would be less likely to show an effect than dietary studies that had higher amounts of NDMA in the dietary studies. You never looked at that or saw that in Madigan's report?

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A. I don't recall, sir.

Q. That wasn't something that was important to you in terms of the findings or conclusions that you made in your report, correct?

A. I'm sorry. I missed a few words in the beginning. Could you say it again, please.

Q. I said that wasn't something that was important to you in the findings or the conclusions that you made in your report, correct?

A. Yes, if I didn't say in my report, then it is -- I either say it is not relevant or something I don't think is important.

Q. And comparing the amount of NDMA in the valsartan pills compared to the amount of NDMA in the dietary studies, that also wasn't important to you in the findings or the conclusions that you made in your report, correct?

A. Well, first I have a concern how can we use the dietary study even

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infer the issue on the impurity of valsartan. I have a hard time to extrapolate the result from the dietary studies or occupational study to purity -- impurity valsartan study.

Q. And you're not a toxicologist, correct?

A. No, sir.

Q. So you're not commonly experienced in looking at contaminations or carcinogens or toxins in one source and trying to make conclusions or assumptions of that contamination and the amount of that contamination in another source, correct? You don't do that?

A. Not for the contamination, but I have involved in many, many Phase I trials for drug development which started with animal study. We figure out is it highly significant, right, for the new compound.

But unfortunately when we transported this model to human beings, sadly, most didn't work. We cannot even

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transport the animal study result to human beings either.

That was my understanding beyond the use safety, right, or contaminant. I didn't deal with contaminant issues before.

Q. Now, let me rephrase that. I see how you thought of animal studies. So I'm just speaking of human epidemiological studies.

You're not commonly -- you're not experienced in looking at contamination or carcinogens or toxins in one source of epidemiological studies and trying to make conclusions or assumptions of that contamination and the amount of that contamination in another source. That's not something that you do, correct?

A. I don't, but, sir, if you allow me to say one thing. Even within the dietary studies, the studies are so heterogenous, you know, as Dr. Madigan indicated in his report, also deposition,

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right, even Song, S-O-N-G, paper, the meta-analysis, they actually admitted even the study involving meta-analysis is so different, right.

If you look at the forest plot of meta-analysis by Song, you can see it. The effect size, even statistical significance, the changing back and forth around this null value, which is one, odds ratio, or OR.

You know, that indicates even with the dietary study, I cannot use the result from the one dietary study to another one, right. Easily it's not applicable.

That's why they use meta-analysis, to try to combine the information to go together, get a single summary to tell us if there is something going on with this -- with the contamination.

Q. Okay. Let me see if I understand your testimony.

I believe you are agreeing

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with me that you're not experienced in looking at contamination or carcinogens or toxins in one source of epidemiological studies and trying to make conclusions or assumptions of that contamination and the amount of that contamination in another source. That's not something that you do, correct?

A. Correct. I don't do that.

Q. So I think what you're telling me is your concern is that, even looking at the dietary studies, there's so much heterogeneity and other issues with those studies, that you don't believe you can extrapolate even to other dietary studies, those findings, correct?

A. To valsartan, yes. Okay. Yes.

Q. Right. Not just to valsartan, but even to other, you know, dietary issues. So if your question was, does NDMA in diet cause cancer? You would raise, there's too much heterogeneity between the dietary

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studies, and model fit issues and other things of that nature, that you don't think the dietary studies could even answer the question, does NDMA in diet increase the risk of cancer, right?

A. Yeah. For a specific population. If you ask yourself, for this particular population, can you tell me I have such contamination for NDMA, right, I say, well, I'm not for sure how to answer your question, right. Even if I use meta-analysis, I cannot, right.

Basically we cannot even pre-specify population. You telling me, and those people what is the number, you know, max number, whatever you want to define as the cutoff, ratio or whatever the number is, that is applicable to everyone or to this particular population, right. We don't know. We cannot even use meta-analysis to helping us.

Q. When you say population, you don't mean United States, because we're

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looking at people from the United States, versus other countries, correct?

A. Yeah, I'm talking about population. For example Danish population, those are using so-called Danish the -- registry database, health -- so-called health registry. That's their population that they're talking about.

Then you talk about the German study. And those guys deal with insurance companies. That's the population that they're talking about.

So every study population, they have well defined population, right, of subjects they followed. So that's what I'm talking about in population.

Q. So you would have difficulty taking the findings, for example, in Pottegard, a Danish population, and giving meaning to what happens in the U.S. population. Is that what you're saying?

A. Yeah. I agree -- agree with

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that. I'm saying -- you're absolutely right. I cannot saying Danish findings is automatically transportable to U.S. particular population. We don't know that. We have no idea.

Either way, I cannot -- like I said before, sir, even with the two studies, we -- we know they directly address the issue, right. However, like every observational study, they had a limitation, right. So we don't know how we can actually say definitely today, sitting here, say impurity of valsartan really caused the problem or not. We are not in a position even to make a decision right now. We really need a very well conducted prospective study, not probably with the valsartan contamination or impurity population because that's impossible to do anymore, right.

So that's the issue we're facing. We need to collect more data. And we need more studies.

Almost every paper that

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Dr. Madigan cited in the dietary study, towards the end of the day, you know, there's one line, they said there's limitation. We should conduct a prospective study, a long-term follow-up.

That's what they are saying. Unifying words. You know very well, because you read those papers. Worried about words, right.

Q. So it's your belief that without that prospective study, it doesn't matter how much contamination there was in the valsartan pills, we wouldn't be able to study the issue, right, because we can't do a prospective study at this point?

A. Well, I think what -- if you allow me to say a few words. If I were -- had a choice, having a choice, I said either you follow the Danish population a little longer, right. Unfortunately, those population, the patients will be contaminated by other things, right.

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Maybe they started eating a lot of food with contamination, et cetera, right. So we do need longer follow-up, even though the study has 4.5 years immediate follow-up. It's pretty long.

But on the other hand we cannot really go back to do a prospective study anymore with this valsartan impurity, anymore, right.

So what I think is the best that we can do at this stage, you actually design a trial, for example using dietary, right. And you say let's use a tactic, just like follow the patient from the beginning for many, many years, right, for dietary. And see how much contamination you are talking about, right.

Then you match the dietary population patients closely to your valsartan U.S. population, what kind of patient are taking this impurity contaminate, right, the valsartan. So

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that would probably give us a signal to find out what's going on.

Q. So you would want to design a clinical trial where the patients in the dietary study are being given food that has the amount of NDMA as the amount of NDMA that people in valsartan were getting each day in the contaminated pill, is that what you're saying?

A. No, you cannot afford people taking a certain amount of contamination, right. That's not ethical at all.

But I'm saying first you need to sort it out, if any association with exposure and unexposure, right, or the level of exposure, using dietary study first, right. You cannot force people, say, hey, you give me the equivalence of food contaminant, right, equivalent to valsartan impurity level. I'm not quite sure you can do that, right.

Q. Have you seen anything that suggests that it would take about

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60 pounds of bacon, eating about 60 pounds of bacon a day to get the amount of NDMA in your food that people were getting in one pill of valsartan?

A. Well, I don't know. I never heard about that piece.

Q. Okay. That's something that you would want to know, right?

MR. MERRELL: Objection to form.

THE WITNESS: Well, you know, there are so many news this day. I'm just really not sure how true it is.

BY MR. NIGH:

Q. Well, if you did the math from the FDA, and what they say the amount of bacon and the amount of NDMA is in bacon, and then you looked at the amount of NDMA in valsartan, you could do the math, you could see that it's 30 to 60 pounds of bacon. You haven't done that though, right?

A. No, I have no idea. Again,

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I'm not a toxicology or epidemiology.

Q. Okay. What do you know about new user designs?

A. Well, in the Danish study, the authors did some sensitivity analysis, also called supplementary analysis. And one thing they did are called incident to users. They don't use the word "new users." But anyway, that's a similar term.

So they are talking about for the new users they do analysis between the two groups, one is exposed and unexposed. That's my understanding.

Q. Right. "New user" and "incident user" are terms that are used commonly to talk about new user design or incident user design, those are used interchangeably, correct?

A. Well, we -- it is interesting. I think we use -- incidence is a more mathematical term. And using new user is sort of like ordinary language.

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Q. Okay. One is more technical you think and the other -- or more mathematical and the other is ordinary language, but they are discussing the same thing, correct?
A. That's my understanding, sir.
Q. Okay. And is it your understanding that --
A. I have some of my -- I'm bleeding.
MR. MERRELL: Do you want to take a break?
THE WITNESS: No, no, that's okay. I just scratched myself.
You talk to lawyers you get nervous, right, so I started scratching. If you allow me to call your first name --
MR. NIGH: Sure.
THE WITNESS: You are pretty tough lawyer, aren't you, right, you are famous for.
BY MR. NIGH:

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Q. Famous? Oh, like -- Bill Nye the Science Guy.
A. Well, anyway. Sorry, I apologize.
Q. Okay. Let's take a look at -- my question is, in the last ten years, aren't there, you know, a lot of studies that are out there talking about that it's helpful or useful to do new user or incident user design in observational studies?
A. Well, the only thing recently, I did -- helping a company figure out using this so-called EPO equivalent. I don't know if you know this EPO, this compound.
We actually helping chemo patients, right, their hemoglobin level is too low, we're giving them this EPO, and it jack up their red cells. Also the hemoglobin level, right. So there is other alternative right now, and I'm helping a biotech company to analyze the data with the so-called incidence

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dialysis patient. That means there's a newly -- newly go to treatment for dialysis patient.
Even in the beginning, they didn't use it, right. Then during the trial start to use it.
So we are very interested to find out the incident users they not have any benefit by taking this oral EPO equivalent compound.
Q. Okay. Describe the benefits or advantages of using a new user design or incident user design?
A. Well, I think somehow, I'm not quite sure in this case, why this incident user becomes interesting.
I would say the primary endpoint is for entire population, right. They have 5,000 patients available in the database. That's their primary endpoint.
Then afterwards they can do other so-called secondary analysis. For example, this is called a subgroup analysis thing.

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So they can pick up anything they wanted to, right, the incident users or something else. People do all the time. But see the problem is for the subgroup analysis, we have to be careful how to interpret the results now. Because you cannot use a .05 anymore for all the subanalysis, right. And that will be exactly falling into this multiple comparison problem.
So if you talking to people, subsequent analysis, yes or no, people always tell you, you have to make adjustment. To make adjustment, that's exactly the same thing, we talking about the whole day, multiple comparisons, right. So you have to be careful when you interpret a result for all the subgroup analysis.
In this case we have to be careful to interpret the incident users, right, what is the hazard ratio, what is it you are talking about, right.
And for example, in this

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case, I believe at a rate of one point something, you know, is not a really pressing hazard ratio.

Q. I asked you if you could describe the benefits or advantages of using a new user design or incident user design. Do you know what the benefits of using a new user design or incident user design when looking at observational studies is?

A. Well, in general, I have no opinion on this, sir. It is case by case. Depend on what kind of compound you are interested in. If something existing for new users, of course that would be a primary endpoint, primary population, instead of using the entire population you are interested, right.

So it all depends on your question you want to answer.

Q. Do you believe that the benefits or disadvantages of using a new user design or incident user design are somehow different when it's the primary

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endpoint or the secondary endpoint?

A. Well, I can -- I have a lot of experience dealing with drug development using so-called experience -- experience means those patients are already using this compound for many months, or something, right.

Now you have a new compound now, right. Then you ask yourself, say do I need to get a naive patient, when I say naive patient means exactly like you said, the new user, right. So when we do a clinical trial, it's always interesting to know, say, are you going to include experienced patient and naive patient.

Most of the time we stratify those two populations, right, to understand what happened if the patient had experience with this compound. And it turns out usually experienced patient, their response for the extended treatment is very low. Basically, they already pick it up by those -- the older compound.

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So in a sense for new users, sometimes you show something -- a big difference between the two groups, treating against control. But experienced sometimes we don't see this very well. The -- I take it back. The other way around. That means the experienced drug, right, the experienced patient using the standard treatment, usually you don't have a very good response, right. But in the new treatment, it's very good.

So the difference is very different. But for the new user, usually we don't see too much, because they sort of balance out.

So it all depend on what you wanted to do. In this case, it's very interesting. The experienced user, if you think about it, right, they probably getting used to it and this is the thought. So you can ask yourself, if you continue using it, what happened. I think both questions are interesting for

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this case.

But I'm not for sure if you want me ranking which one is more important. I don't know. It depend on investigator or clinical question that you want to ask.

Q. In observational studies, what are the benefits or advantages of using a new user design or incident user design?

A. For observational study, I don't know, sir. I know as part of the clinical trial setting. I think probably the same principle apply to observational study.

I think basically, sir, it all depend on your clinical question, what kind of question you want answered.

MR. NIGH: Let's take a look at LP-1578.

(Document Marked for identification as Exhibit Wei-11.)

MR. NIGH: This will be

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marked as Exhibit 11.
Let's blow up the opinion.
BY MR. NIGH:
Q. Actually the a the bottom, we can see that this is published in Rheumatology.
Do you see that? It's published 2015, Rheumatology.
Do you see that?
A. Yeah. It's a little too small for me, sir.
MR. NIGH: Let's blow that up a little bit more, if we can.
We can do each one separately.
BY MR. NIGH:
Q. Do you see Rheumatology, Nature Reviews Rheumatology, July of 2015.
Do you see that?
A. Yes, sir.
MR. NIGH: And now, let's pull up the abstract and the title. Blow up the title. Yeah, right there.

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BY MR. NIGH:
Q. "Opinion: Active comparator design and new user design in observational studies."
And you can see the authors there, right?
A. Yes.
Q. And it says, "Over the past decade, an increasing number of observational studies have examined the effectiveness or safety of treatments for rheumatoid arthritis. Unlike randomized clinical" -- "controlled trials, however, observational studies of drug effects have methodological limitations, such as confounding by indication."
Do you see that?
A. Yes, sir.
Q. "Active comparator designs and new user designs can help mitigate such biases in observational studies and improve the validity of their findings by making them more closely approximate RCTs."

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Do you see that?
A. Yes, sir.
Q. Is this the first time that you've seen papers that discuss using new user designs can help mitigate these sorts of biases in observational studies?
A. Yeah, this is new to me.
Q. Okay. Next, it says -- I'll go to, "This principle helps ensure that treatment groups have similar treatment indications, insinuating both measured and unmeasured differences in patient characteristics.
It next says, "The new user study includes a cohort of patients from the time of treatment initiation, enabling assessment of patients' pre-treatment characteristics and capture all events occurring during follow-up."
Do you see that?
A. Yes, sir.
Q. Are you aware that there were numerous studies over the last ten years that talk about using new user or

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incident user designs in observational studies and the benefits that it provides? Are you aware of that?
A. No, sir.
MR. NIGH: Let's take a look at another one. LP-1567.
(Document Marked for identification as Exhibit Wei-12.)
MR. NIGH: This will be marked as Exhibit 12.
BY MR. NIGH:
Q. Let's take a look at the second page. At the very top, you can see the name of the journal, pharmacoepidemiology and drug safety, published 2013.
Do you see that?
A. Yes, sir.
Q. And it says, in the abstract, "Comparative effectiveness research includes cohort studies and registries of interventions. When investigators design such studies, how

important is it to follow patients from the day they initiate a treatment with the study interventions?

"Our article considers the question and related issues to start a dialogue on the value of the incident user design in comparative effectiveness research.

"By incident user design, we mean a study that sets the cohort's inception date according to patients' new use of an intervention. In contrast, most epidemiological studies enroll patients who are commonly or recently using an intervention when follow-up began."

Now with this, Pottegard had the ability to do a new user design analysis. Had they made the decision to make that their primary endpoint, the data would not have changed for that analysis, correct?

A. You mean they're going to switch the incident users, the subgroup

as the population of interest? That's what you're asking me?

Q. Yes. They could have done that?

A. Yeah, well, they could.

Q. And they would have all the data to have been able to report on what the findings would have been for the new user analysis, correct?

A. I believe so. They did a sensitivity analysis using the subgroup analysis.

Q. In looking at Page 5, Number 4 -- actually, below, on the left side it shows recommendations for reporting.

Do you see that?

Recommendations for reporting.

And Number 4 shows, "Investigators should conduct sensitivity analyses with varying definitions of incident use to illustrate the stability of findings with respect to validity and

precision."

Do you see that?

A. Yes, sir.

Q. And that's what Pottegard did, they had a new user design in their study, correct?

A. Yeah. They did a subgroup analysis, a sensitivity analysis.

Q. Are you aware of whether or not Gomm had a new user analysis?

A. That, I don't know.

Q. Okay.

MR. NIGH: Okay. Let's take this down. Let's look at Pottegard. LP-1573.

(Document Marked for identification as Exhibit Wei-13.)

MR. NIGH: This will be marked as Exhibit 13.

BY MR. NIGH:

Q. Now you spent time in your report talking about the American Statistical Association.

Do you remember that?

A. Yes, sir.

Q. And their criticisms of using P-value of less than .05 as a line in the sand, so to speak, right?

A. Yes.

Q. In other words, if a P-value in a study is .051 versus .049, those don't have a large difference in how you interpret that study, correct?

A. Well, it's more than that. Even you can stretch out a little bit. You know, even say .07 and .04, aren't different enough. Basically, they are the same.

Q. Okay. I think you used also, if they are .07 and .04, they're going to have a similar effect.

Now -- right? I mean, in terms of your interpretation?

A. Hold on. Hold on a second, sir. Sorry to interrupt you.

The American Statistical Association, if you read it very

carefully, they are just telling us, don't use a single metric, which is P less than .05, to make a black and white claim for the statistical significance.

We should utilize other judgment, for example, from clinical input -- clinical input, right, and from subject matter people.

And we all know very well when Dr. Madigan in his deposition, the defense lawyer showed us ASA statement line by line. Everything, she ask Dr. Madigan, "Do you agree with ASA statement?" And Dr. Madigan always say yes.

Okay. So, basically, he agrees with ASA statement, saying we should not use P less than .05 or 95 percent confidence interval, excluding null value or not, to make a decision. And broader, we should look at the entire totality of evidence to make a decision.

So that's the point. So the P-value is the what. You know, it's not

that interesting. You should provide more information to telling us this case, telling actually a lot of information regarding the impurity of the valsartan or not, right.

Q. I understand. In terms of interpreting data from a single study, if it has a P-value of .04 or a P-value of .07, as you spoke, your interpretation or the weight that you give to those, there's no bright line rule that says .05 makes the finding important, or under -- or over 0.5 makes the finding not important, correct?

A. That's correct.

Q. Now, if the P-value is .04 and the other P-value, versus a P-value of .00001, you don't believe that the American Statistical Association is saying to ignore a P-value of .0001, as you think about the effect that that had in that study, correct?

A. Oh no, no, sorry. This is misleading. You see a study with a huge

sample size like cardiovascular trial. As you know very well, right, cardiovascular trial, they involve thousands and thousands of patients, right. So even your treatment, the group difference is so small, the P-value is very, very small. Because basically a tiny little difference will grow up the P-value or grow down the P-value, right.

Everybody knows the fact, we have the cardiovascular trial, we have a wonderful P-value, but the clinical utility is very little. I can give you many, many examples.

But in any event, in a rare disease, for example, the sample size is limited. If I have entire world have 500 kids, they have a problem, you said well, I'll tell you what, I use 400 patients in the study.

Basically you use entire population now. Even the P-value you know because the sample size, the population size, you're now going to get

.0001, but you're going to see clinical utility, right.

So I don't think we should have used a P-value of .001, versus .004. .01 is highly significant. It must be a lot of clinical utility, right. It's not true at all. This actually contradicts what we are thinking. That is the problem of using P-value.

I bet you a dollar if I ask you to explain to me what a P-value is right now, I think you have a hard time to explain to me, right. Most clinical people have a hard time to understand what a P-value is. Basically, they don't even understand P less than .5, okay. So because the traditional way, in the appropriate way, when everybody using P-value .05 is for convenience.

But anyway, sorry for this long response to your question.

Q. I wouldn't make assumptions about what I know for P-value, okay? I think that's inappropriate for this

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questioning.
But my question is, as you're considering the weight of a particular study, if a P-value is .04 versus a P-value of .0001, you would give more weight to the study that has a P-value of .0001 than you would to the study with the P-value of .04, all things else equal?
A. You're saying .04, in the same population, the same treatment, the same control, is that what you're saying?
Q. Everything else equal. Just looking at the P-value between those two studies.
A. If they are identical studies, one got a .04, and the other one .001, we are in trouble. That means highly significant difference. How come you can translate the first study with .04? Then we have really concern now, right.
That means FDA always ask you to do two studies, confirm your

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so-called significance. Now you are in trouble. One isn't so significant, the other one is mediocre. What are you going to do? It's inconsistent.
Q. As you interpret P-values, is it your statement that you don't think that a P-value of .0001 in a study has more effect or more weight than a P-value of .04?
MR. MERRELL: Objection to form.
THE WITNESS: When you say treatment affect size, you see you go back to clinical utility, or clinical effectiveness, right.
Your .001, and you -- probably the difference only save the patient a couple weeks, but with huge study, you got a .0001, right.
Then you say .04. If I gave you the differences of say, two months, you say wow, which one you really think we have more benefit,

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is the first study with .04 or the second one with .0001.
You see the problem in utilizing P-value as the sole metric to make a decision, you don't have the scientific evidence at all. You basically just tell me the probabilities then, right, which is not very helpful.
BY MR. NIGH:
Q. So as you interpret the study, and you see a study that has a P-value of .04. And another study -- and I'll be very clear. I'm saying a P-value of .0000001, okay?
You wouldn't put more interpretation or more weight on the finding that has a P-value of .0000001 than you would the one that has a P-value of .04?
A. I need to look at the confidence interval of the two studies. The first one, your confidence interval is very tight. For example, hazard

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ratio, right. Your hazard ratio is like a .99, right, but because your P-value is so good, your other finding of .998 is still below one. You say, wow, look, this is highly significant. But a hazard ratio of .99, that's almost close to one, right.
Then the other one is the confidence interval 95 percent. You say wow, look, the hazard ratio is a .7. The other finding is .95, right.
So which one you prefer?
You need more -- you need more evidence to enter in the P-value, right.
Q. Sure. You would want to see confidence intervals as well. But looking at just the P-value --
A. Yeah.
Q. -- of .04 versus a P-value of .0000001, you can't make any comparison between the effect you would have just looking at P-values?
A. No. You look at a

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confidence interval, that would tell you exactly the size of the difference. Many times what is the effect of size, what is the effect of size you are talking about. It's not only the P-value matters anymore, right.

P-value is giving you the first hurdle. You pass the hurdle. You say, well, you know, it looked like my assumption -- there is no difference between two groups. That's your assumption. You reject this assumption. You say, what is the probability, I observe this extreme value, I observe the hazard ratio of .99, right. What is the chance it is .00001. Because you have thousands and thousands of patients, right, so obviously you can detect a tiny little bit of difference of .99 from one, right. I said who cares, who cares about the difference of .01. But because your sample size is so big, you've got such a good P-value. But I said wait a second, let's look at the size of your -- the

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group before we jump into the conclusion.

Do you think that's more informative than to only use P-value?

Q. I think in my question -- you keep jumping to changing the effect size. I haven't told you effect sizes yet. I've only asked you to look at P-values.

I'm not sure why you keep trying to bring -- hold on, hold on. Let me ask my question.

A. Okay.

Q. I'm not sure why you keep trying to bring the effect size. It's almost like a gotcha moment.

What I'm telling you is, in this next question, since you have difficulty just looking at the P-value and want to run to effect size, my question now is, if the effect size is the same in both studies and one has a P-value of .04, and the other one has a P-value of .0000001, would you interpret those any differently?

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MR. MERRELL: Object to form.

THE WITNESS: Sorry, sir, you are changing your story now. You're saying solely based on P-value multiplication. Now you are telling me the two studies are the same size, right.

If the same size, the confidence interval is .04 is wider, right, then the P-value of .001, right. Of course, I said choose the one that is .001, because you already told me they have the same size. That's extra information you're giving to me, right.

BY MR. NIGH:

Q. Let's take a look at Pottegard.

Okay. If you take a look at Page 4. Direct your attention to the bottom of the first page, the writing there. You can see that paragraph there,

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and on over to the second -- to the left column where it says "Results Comparable."

MR. NIGH: If we can blow that up to the next paragraph. Just the next paragraph. I don't need all the rest of that. So we can blow this up bigger.

BY MR. NIGH:

Q. When you look at this, you can see "Results comparable to the main analyses were found when we stratified by sex and age, whereas a stronger association was seen when we restricted to incident users during the study period (hazard ratio of 1.58 with a confidence interval of .99 to 2.52) 95 percent confidence interval."

Do you see that?

A. Yes, sir.

Q. So they report on a 1.58 hazard ratio with a confidence interval that just barely crosses one, correct?

A. Yes, sir.
Q. And had they set out as the primary endpoint to be new user design or incident user design, they would still have that same finding, hazard ratio 1.58 on this population, with a 95 percent confidence interval of .99 to 2.52, correct?
A. Yes, sir.
MR. NIGH: Okay. We can take this off -- off the screen.
Actually, let's put Pottegard back up.
BY MR. NIGH:
Q. As you looked at Pottegard, did you ever wonder or ask the questions, was there contaminated products that were being announced after the publication of this study?
A. I don't know.
Q. Okay. The point of Pottegard is to compare uncontaminated group to people who were possibly contaminated or probably contaminated,

correct?
A. Yes.
Q. So already in that study design, we don't have a true test in that study design, because even the people in the test group are defined as possibly or probably contaminated, right?
A. Yes.
Q. And to the extent that people who are put into the test group that were actually not contaminated, then that would -- that would lead to bias toward the null in the study, correct?
A. Let me go little slower. You're saying the control arm supposedly, not a contaminant, that's a control arm, correct?
Q. No, no, the test group. The test group is defined -- the test group is defined as possibly or probably contaminated, right?
A. Yeah.
Q. And so if that test group included patients or subjects who

actually did not receive contaminated valsartan, then that would lead to bias towards the null, correct?
A. Well, if you already have this idea, the impurity in valsartan is really hurting us, right. You don't know that. You're running around in a circle right now, right?
You're saying, well, now suppose this impurity is really hurting us for sure, right. Then you're saying, okay, I tell you what, part of this contaminated group, actually they were not contaminated, right.
You already said that you were higher bias against this impurity. You know what I'm saying?
If you actually truly believe the impurity in valsartan is harmful, you don't have to do a study. You just say good-bye. I don't need any data.
But now you're saying, well, wait a minute, let me just argue with

you. If this contaminated group, some people did not have contamination, you're saying that you actually bring this towards null.
I say well, you already believe the impurity is hurting people, right. That's your assumption, correct?
Q. Do you know what bias towards the null means, as that terminology is used to review epidemiological studies?
A. Well, that's statistical terminology. It's not really an epidemiology term.
Q. What does bias toward the null mean as you're reviewing epidemiological studies?
A. You mean the difference between the two groups tend to be smaller than supposed to be. That's close to the null value. That's what you're saying. It's all common language.
Q. Your belief that when using the terminology "bias towards the null"

or that certain things would cause bias towards the null, what do you think is meant by that?

A. Well, bias towards the null means that you are in favor supporting the null hypothesis. The null hypothesis in your case means impurity in valsartan has no association with cancer incidence. That's your null hypothesis, okay.

Now, you are saying, look, if I do an analysis, bias towards null, that means that your analysis result actually helping me to demonstrate there is no association. That's what you're saying. That's what you -- your case you are talking about, right, that's bias to the null.

Q. So in an epidemiology study, when certain things occur that would lead towards bias toward the null, what is your interpretation as to bias toward the null in that setting?

A. All right. Let me make it clear, sir. I'm not speaking with this

so-called degree of contamination or contaminant, whatever you want to use, the word, right. Even the treatment or testing group. You say some patient didn't even take it, the impurity, right. Let's forget about this.

In general, in general I say what do you mean by a study biased towards the null? That means that your study result actually helping me to actually saying we cannot reject your null hypothesis, right. It's not very powerful to reject a null hypothesis. That is what exactly you are talking about, bias towards the null.

Q. That's not what I'm talking about. So let me explain.

When certain things occur in a study and they lead toward bias toward the null in that study, doesn't that -- doesn't that infer that you're basically watering down the results towards the null when certain things happen in a study?

A. Sir, listen to me. That's exactly I'm saying to you. You lose the power of detect -- you reject the null hypothesis. That's the same thing you're saying.

Q. I see. So when you're losing the power to reject the null hypothesis, that would -- that would --

A. Yes, that would be -- yeah.

Q. When you include subjects in the test group that don't have -- that did not take contaminated valsartan, you would lose power to be able to reject the null hypothesis, correct?

A. That's in general term, bias toward the null, sir. That's exactly the same explanation as you did, right. You did it much nicer than I did, right, because people don't understand the power. But you understand.

Q. Yeah, let me ask this again. When you include subjects in the test group that do not have or did not take contaminated valsartan, you would lose

power to be able to reject the null hypothesis, correct?

A. Correct.

Q. Now, on the flip side, if you included in the control group, patients who actually took contaminated valsartan, you would also lose power to be able to reject the null hypothesis, correct?

A. Yeah. Either way. Either way you have a bias towards null.

Q. As you reviewed the Pottegard study, did you understand that even in the way in which they defined the test group, that they would be including patients who never took contaminated valsartan in the test group?

A. I don't know that a fact or not. But even suppose hypothetically that happened, but, sir, if you think about any observational study, we have so many confounders. You have so many unmeasured confounders, you probably don't make a good adjustment, make the

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two groups comparable.
You know, this one thing is also a confounder. We have no idea how much confounding effect what you describe to us, right.
So this is part of it for observational study, basically have issue now, right.
And that's why I said many times, I'm not in the position to say impurity in valsartan has nothing to do with the cancer incidence at this stage, because we don't have a well-conducted prospective study, right. Because that's not the case. So that's what is my position.
You can't say, well, the contamination is probably all messed up. I say, well, sorry, that is one of the confounders. Well, you can consider other confounders. I can tell you this is probably not an interesting confounder setting, right, balance between the groups. Probably is nothing, right. So

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basically I'm not worried about this.
Q. Let's -- let's talk about that, the weight of confounding based on the study design.
MR. NIGH: Let's pull up "Participants" on the first page.
BY MR. NIGH:
Q. You don't know -- in terms of understanding the weight of confounding based on the study design, you would want to know how many patients that were contaminated, taking contaminated valsartan, got put into the no exposure group, and then how many people got put into the control group or no exposure, and then how many people who were taking -- who never took contaminated valsartan got put into the test group. Like you don't know -- you don't know the numbers in each of those groups, right?
A. Yeah, if you say you switch them around, we don't know how many guys. Actually this is classified. This is

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very common in clinical study. When we classify those guys, right, yeah.
Q. This classification error can be one of the worst errors in a study design, correct?
A. No. I disagree. It depend on how much you have a misclassification, right. A tiny little bit doesn't really matter much. Other confounders are probably highly correlated with outcome.
Q. I'm glad you mentioned that. It depends on how much misclassification you have, right?
A. Yeah.
Q. Now, if we look at the study, we can see that the study end date is June 30, 2018, do you see that? "Participants were followed from one year after cohort entry until experiencing a cancer outcome, death, migration, or end of study period (June 30, 2018.)"
Do you see that?
A. Yeah.
Q. If we blow it out, we come

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back, I'll show the date of this, we can blow that up as well.
And we can see the accepted September 9, 2018. Do you see that?
A. Yeah.
Q. So after June 30, 2018, and after September 9th of 2018, do you have any idea how many products were recalled and found to have contaminated valsartan either with NDMA or NDEA after the conclusion of this study?
A. I don't know, sir.
Q. Would it bother you if more than 50 percent of the products that were thought to be uncontaminated were actually later found to be contaminated in terms of the study design?
A. I don't know the number you are quoting there, sir.
Q. Well --
A. But I think --
Q. -- are you aware that Torrent announced their contamination after the end date of this study, are you

aware of that?
A. No, sir.
Q. Are you aware that Hetero announced their contamination after the end date of this study?
A. No, sir.
Q. Are you aware that Aurobindo announced their contamination after the end of this study?
A. No.
Q. Are you aware that there were multiple other companies in Europe that announced the contamination of their products after the end of this study?
A. No, sir.
Q. Wouldn't that be something that you'd want to know in terms of understanding just how much the misclassification error has impacted the findings of this Pottegard study?
A. Well, that's a very good question. How come Dr. Madigan didn't include in his report then. If you think this is such an important issue, how come

you don't take to put into the report.
Q. Dr. Madigan -- Dr. Madigan is not an epidemiologist. He didn't --
A. Well --
Q. -- for a reason.
A. Okay.
Q. Okay? Did you see that Dr. -- - sorry.
Did you see Dr. Etminan included this in his report?
A. No. I said I just glanced over it. I didn't read it carefully.
Q. Did you see --
A. But I'm saying --
Q. Did you see that several of our other experts also included this in their report or no?
A. No, ma'am -- no -- yeah.
Q. Okay. You asked why Dr. Madigan didn't include it in his report. But did you see these other experts included that information in their reports?
A. Well, sir, my assignment is

only dealing with Dr. Madigan's report. I'm not responsible for your other reports, right. Why should I put all my energy -- sorry?
Q. Dr. Madigan didn't have Gomm or Pottegard. You made the decision to include Gomm and Pottegard in your report.
A. You're telling me, other guys, expert witness, they know the existence of those two studies. How come those guys don't communicate with Dr. Madigan, "Hey, Dr. Madigan, there were two studies that directly address the issue the impurity of valsartan." How come they don't --
Q. I don't -- I don't think you understand the purpose of Dr. Madigan's report.
Dr. Madigan never gives threshold. He never gives conclusions on causality, correct?
A. If there is no causality, what's the point to submit a report?

Q. Okay. Did you read his report to get what the point of his report was?
MR. MERRELL: Object to form.
THE WITNESS: Yeah, I mean, he basically told us that there's an association from the dietary study, from an occupational study. But he admitted he couldn't even translate association to causality.
But here you are. You're looking for causality. You say, sorry, I cannot answer your question because basically I cannot answer causality question.
I say, wow, okay, why do we need to bother Dr. Madigan, he's a busy guy, to write a report, right.
If your epidemiologist can answer this question, why do you need Dr. Madigan then?

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BY MR. NIGH:
Q. Why do you think we used Dr. Madigan?
A. I don't know. I'm very curious. I mean, if he in his deposition said, ma'am, we cannot answer causality question.
The first thing I said, well, good-bye. If you cannot answer causality, why should I need you on the panel, right?
Q. So you would discard his conclusion because he's not answering the question of causality? You would say good-bye, why should I need you on the panel?
A. Sir, don't put your word in my mouth. I'm trying to say he couldn't even establish association. And then he had admitted in public he cannot answer the causality question, okay.
So my question for you, if you cannot even say the impurity of the valsartan caused the cancer, then what is

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the point for whole case then?
Q. Do you believe that you can answer the causality question?
A. Sorry?
Q. Do you believe that you can answer the causality question?
A. I can't. That's why I don't work for you, unfortunately. You know, you're a very good lawyer. I know there is a problem. We cannot establish causality.
If I can, sir, you know, I'd be famous. I would get a Nobel Prize winner. Nobody actually can jump in association to causality that easily. You need clinical input. You need all kinds of people, toxicologists, right. You cannot rely on statistician to tell you there's a causality.
Q. Okay. So are you admitting in public now as well that you cannot provide a causality opinion either?
A. I didn't say any causality, sir. I didn't say any causality. I

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didn't helping you to say, well, impurity cause cancer.
Q. You don't have a causality opinion one way or the other though, right?
A. Why should I need another part? I cannot even establish an association between the impurity and the cancer risk. I cannot even demonstrate either way. How in the world we can actually jump into the wagon and say there's a causality.
For my part in this, there's no causality issue at all.
Q. Did you review Dr. Panigrahy's report at all?
A. No, I don't think so.
Q. Okay. So as far as you know, sitting here today, you have no criticisms of Dr. Panigrahy's report or the LCEs that he calculated, correct?
A. You mean Dr. Madigan computed LCE?
Q. No. No. My question was

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not about Dr. Madigan. It's about Dr. Panigrahy.
As far as you know, sitting here today, you have no criticisms of Dr. Panigrahy's report or the LCEs that he calculated, correct?
A. I didn't read his report. How in the world I can say I criticize or not criticize. It's not a logical question, right?
Q. I think it's a logical question. I think you're agreeing with me.
Because you never read his report, you don't have any criticisms regarding Dr. Panigrahy's reports or the LCEs that he calculated, correct?
A. Better way to say, I have no opinion of this. I don't say I'm not going to criticize. Which way -- because I don't know which way he did. So I have no opinion. I cannot make any comments.
If that's a better way to answer your question?

Q. Yes.
MR. NIGH: Okay. We've been going on for a little bit more than an hour. Let's go ahead and take a break at this time.
THE VIDEOGRAPHER: The time right now is 4:24 p.m. We're off the record.
(Short break.)
THE VIDEOGRAPHER: The time right now is 4:44 p.m. We're back on the record.
BY MR. NIGH:
Q. Now, Doctor, in your report, you provide no information on the background rate of exogenous NDMA from sources such as diet, beer, or smoke, correct?
A. Correct.
Q. And in fact, that's something that you hold no opinion about or you don't have any knowledge in terms of the amount of nanograms or the amount of exposure that people have to exogenous

NDMA from diet, beer, and smoke, correct?
A. Yeah. I have a hard time even past the first hurdle, association question. I think the next step, I can't even understand how we can establish.
Q. And also in terms of endogenous NDMA, you have no understanding or any -- you haven't looked at any materials that describe or explain the amount of endogenous NDMA or even endogenous nitrosamines, correct?
A. Correct.
Q. Okay. Let's take a look at your report.
MR. NIGH: It's LP-1557 we're going to take a look at Page 17. Actually Page 10, Paragraph 21.
BY MR. NIGH:
Q. Here you say, "Even if we can claim we collected all of the relevance patients' baseline factors, the modeling of the adjustments for those factors may be questionable since the

standard lack of fit test for the model fitting does not provide clinically meaningful interpretation via a P-value of the test."
Do you see that?
A. Yes, sir.
Q. Do you recall giving similar opinions both in Taxotere and Celebrex as this?
A. Sir, I don't recall.
Q. Okay. Next you say, "For example, in a publication by Dr. Madigan, heavily cited in his report, Loh, et al., claimed that dietary NDMA intake was significantly associated with increased cancer risk in men and women via Cox proportional regression, adjusted for age, sex, BMI, cigarette smoking status, alcohol intake, energy intake, physical activity status, education level, and menopausal status in women."
The Loh study adjusted for numerous potential confounding factors, correct?

A. They tried. Dr. Loh was trying. Was trying.
Q. Now, what you say next is, "However, it is not clear a thorough model fitting assessment was conducted."
Do you see that?
A. Correct.
Q. You next say, "If the Cox model does not fit the data well, it is known that the resulting hazard ratio does not have clinically meaningful interpretation."
And you put, "For this situation, the conclusions of the study and inferences drawn by Dr. Madigan based on the study would be invalid and inherently unreliable."
Do you see that?
A. Yes, sir.
Q. Are you stating that Madigan shouldn't rely on Loh because it is not clear a thorough model fit assessment was conducted?
A. Well, sir, this is beyond

Loh's paper. Almost every paper, study, Dr. Madigan cited in his report. Sort of lack of assessment of a model fitting.

Q. I understand. I'm asking you just in regards to Loh. Are you stating that Madigan shouldn't rely on Loh because it is not clear a thorough model fit assessment was conducted?

A. That is my opinion.

Q. You recognize that the vast majority of observational studies do not include in the study or provide a comprehensive description of model fit assessment, correct?

A. I'm sorry, sir, you say most observational study won't including --

Q. I'm saying you recognize that the vast majority of observational studies do not include in the study or provide a comprehensive description of model fit assessment, correct?

A. Well, at least for those papers that I read, they didn't give us a very thorough assessment. I don't know

in general, sir.

Q. Well, in general, approximately what percent of observational studies do you believe provide a comprehensive description of model fit assessment?

A. I don't know. But for all the studies Dr. Madigan cited, I look at carefully. I couldn't find it. I mean that only concerned me. I don't really concern about other observational studies.

Q. You don't know whether or not the vast majority of observational studies provided do not provide a comprehensive description of model fit assessment?

A. Well, sir, if they didn't provide it, that means that the result is not believable, right.

Q. So --

A. That's a common --

Q. Go ahead, you can finish.

A. It is common sense, sir. If

you cannot tell me if the model adequately fit your data. I said, well, can you tell me -- in fact, you need a validation set, right, to help me, the model is okay or not. You cannot use only one single independent data. The independent data set you fit in the model, right, Cox model in this case, but you have to use another independent observational study to validate the model before clear or not. That is a well known fact now, right. The training, the validation set independent of datasets.

Q. Let me be a little more clear about my question.

When I am talking about vast majority of observational studies, I don't just mean these dietary studies. I mean the vast majority of observational studies that are done do not include in the study or provide a comprehensive description of a model fit assessment, correct?

A. Well, sir, I don't know

exactly the percentage you make in this. But I'm really sorry to see that, right. You are very smart lawyer.

If you're actually doing a study without validating your assessment appropriate of model, how can you sell your model to outside world?

Right. I mean there are tons of papers, they all junk papers, everybody knows that. Right. You publish a paper with all kinds of confounding, you can find out go fishing trip, or whatever, cherry-picking, you pick out a set of variants, you make adjustment, you got a decent P-value and say I'm done. You see that's the problem, right.

If you cannot tell me your model is okay, you can do anything you want to, tell me the story. I don't even know if the story is okay or not okay, right.

Q. So if the vast majority of observational studies do not provide a

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comprehensive description of model fit assessment, then you would disregard those studies?

A. Yeah, basically I think we don't really believe this kind of study anymore, right.

I mean, you know, you are a good law firm. Dr. Madigan is a distinguished statistician. And we need a very high standard, right, to conduct an analysis of observational study, right.

Model checking is very important step. Without it, we cannot do anything, right, down the road.

Q. And in the absence of that very high standard of conducting an analysis of observational studies, you believe that you cannot demonstrate an association between NDMA and -- NDMA in the diet and cancer, correct?

A. Yeah, I can play game with you, say, doctor. You see the Loh paper, he lists so many so-called covariates,

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right, which is baseline variables.

If I have raw data, I can play game and delete some covariates in the model or adding something else, he didn't include it. I bet you I probably can play the game with you, turns out my P-value is greater than .05. But that's an association problem, right. That's the problem.

Everybody can manipulate a model and tell you a story. They want you to listen to story.

Q. Is that your belief, that Loh could have played games and simply gotten a P-value that was greater than .05?

A. Sir, this is so common. That's why it will be hazard ratio is so low. Usually we say, well, look, you can manipulate your adjustments, okay, you can make adjustment and make your P-value significant. We can make adjustment, make your P-value not as significant, right. That's a well known fact. That's

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why people usually don't believe observational study.

It's like for example, Covid-19, the pandemic, right, in the beginning people submit all kind of observational studies, say oh, yeah, you know, this treatment is great, especially our former president, right. He said without any evidence, hey, let's see, this observational study show you this is very good treatment. It turns out in the clinical trial, we don't see anything.

So you see, the society now, they don't believe observational study for the Covid-19 anymore. You say without a clinical trial, forget it, I'm not going to use your treatment, even if you have observational studies that will state the statement of fact.

See, this is what happened, right, in the last 18 months. You know better than I do, right.

Q. All right. Let me see if I've got your testimony right.

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In general you believe that you can't believe observational studies, correct?

A. If you have really nice recent protocol, pre-specified adjustment, then I have a training set to fit in your model. I have a validation set to validate what you claim the model is okay or not. Then I believe you have a story to tell. You have a valid story to tell us, right.

But right now, like you say, I don't even give you the details, how do I select this baseline covariates with adjustment. How do I select the spec? I have no idea how you select. How many covariates are you not including in the covariate adjustment. I don't know, right. You just publish.

Now, papers that are published in the -- very few people even pay much attention. Very small group of people, oh, yeah, yeah, yeah, this is interesting. But in reality, people

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don't take this seriously without a rigorous assessment of your model of what your process you are talking about, right.

The -- this is actually -- you know, we need to hold a high standard, right, for this legal case. You can't set a legal case example in the future. How do we defend the people, right. You have to defend the people in the right way, correct way.

Q. Are you aware that most FDA recalls have been prompted as a result of observational studies and not clinical trials?

A. I don't recall, sir.

Q. Have you ever seen data that demonstrates that?

A. I saw many cases FDA had some concern about safety issue of -- for example, and you finish Phase III trial, right, you want to demonstrate your treatment is okay. But FDA still concerned about the long-term toxicity

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profile. Usually they ask the company to do a marketing Phase IV trial to figure out, do you have the safety issue. That's very common. You know, for example, we did that important E-P-O, EPO, 2000 -- 11 years, to actually sadly say EPO is not safe.

Q. Right.

A. So you see people doing that. But I don't know exactly for this case, sir, any like contaminant or impurity in valsartan and what the FDA did, I don't know.

Q. In general, have you ever seen data that most FDA recalls have been prompted as a result of observational studies and not clinical trials?

A. Well, that's why people criticize the result, right.

Q. I'm sorry. That's why people criticize the FDA recalls?

A. No, no, no. You're saying the observational study was conducted because the recall. And most of the

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people actually say, well, it's okay. You're telling me, I don't really believe you, right, whatever you say. You know, they don't take it seriously right away.

So that's what happened in this society. You can publish any paper you wanted to. In fact, my friend, is a JAMA Open associate editor for statistics.

He said -- he told me a few months ago, he said that he got lots of papers for different legal case for safety stuff. Everything is observational study, right.

He was so surprised. People manipulate the modeling and actually picking up the model they like and write a paper.

So the editors very carefully now to select those papers. They just want to use JAMA, for example, as a vehicle to tell all sides my drug is safe or not safe.

He decide -- it's not only

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for safety issue. If someone wants to badmouth the other drug company, they also publish papers. So this whole world is flooded with not reliable and misleading studies.

But people publish. If you pay for it, this case, you can publish your papers.

Q. In general, have you ever seen data that most FDA recalls have been prompted by observational studies and not clinical trials?

MR. MERRELL: Objection to form. Asked and answered.

THE WITNESS: I don't recall. I don't know, sir. In this moment, I don't know.

BY MR. NIGH:

Q. I believe it's your testimony that even if the vast majority of observational studies do not provide a comprehensive description of model fitness assessment, you would not give reliability to those observational

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studies, correct?
A. I would put very little weight on their findings.
I don't really trust the result with just single study. I probably need a validation study.
Q. Well, I mean, even if there are numerous observational studies, but numerous observational studies on an issue and none of them provide a comprehensive description of model fitness assessment, you would throw out or ignore the results of all those studies, correct?
A. I say I don't even care if they published those papers or not. I don't take it seriously.
Q. So you would ignore those results, correct?
A. Yeah, unless they have another independent study validating what they are claiming, right. Then I say, okay, that's correct.
Q. So in this situation, when

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Loh doesn't tell you in the study whether or not it used a thorough model fitting assessment, you would ignore the results of Loh, correct?
A. I would probably say I'm not going to take this seriously.
Q. Okay. Okay. Now, let's take a look at Zheng. You have the same -- your next paragraph, you say, "As another example about the adequacy of modeling, in the paper by Zheng, multiple logistic regression models were utilized." And then you put again, "It is not clear if the model fits the data well. Again, a lack of fit test for model fitting is not informative since it only provides a P-value."
And so again, because Zheng does not provide a thorough model fitting assessment in the study as to whether or not that was conducted, you would ignore the results of the Zheng study, correct?
A. I wasn't excited about the results at all.

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Q. You would give it little to no weight, correct?
A. Yeah.
Q. And in fact, many of the dietary studies here that did not make it clear that a thorough model fitting assessment was conducted, you would have ignored those dietary studies or given them little to no weight, correct?
A. Correct. But, sir, you notice some dietary studies are very, very old, right, more than 20 years. And at that time probably those guys were not educated well or trained very well statistically speaking. They probably didn't do it. Okay.
But I believe a good well conducted observational study this date, they probably do a very good thorough job to assess the adequacy of the model fitting.
Q. I'm sorry. Many of these dietary studies are not published more than 20 years ago. There's many of them

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that are more recent, right?
A. You have one paper published in 1999, right?
Q. I know, but many of these dietary studies, we've got some that are published in 2019, 2012, 2011, 2012 -- 20 -- 20 -- you know, many of these are published in the last decade, correct?
A. Yeah.
Q. But even then, if they didn't specifically put in the study and describe, make it clear that a thorough model fitting assessment was conducted, then you would have ignored it or given it little to no weight, correct?
A. Yeah, I wouldn't pay much attention to it.
Q. Isn't that the main problem in terms of your concern about whether or not there's association between dietary studies and the NDMA in diets and whether or not they have an increased risk of cancer? Isn't that your main concern, that they didn't include model fit, and

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as a result you've given little to no weight or ignore them?
A. Sorry. Go ahead, sorry. I don't mean to --
Q. That was the end of my question.
A. Okay. No, sir. This is a part of it, right. You can see my report. I have several concerns, right, more than just the model fitting stuff.
My concern also, saying the decisionmaking about so-called statistical significance and we should do better job than that, right.
Even if you have correct model, you should providing more than P-value for that application. That's another concern I have.
The third one is more serious. I said even if I believe what you're saying from these publications, how can we actually convince people you can extrapolate the result from the dietary study or occupational study to

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the impurity in -- in valsartan, right, the issue we are dealing with right now.
That's the issue and my concern.
Q. Yeah, but you don't -- you don't -- you don't do that sort of work, where you extrapolate results from one exposure to another exposure setting, correct?
A. I think we have to be very careful to actually figure out how we can use one type of study, and we can extrapolate the result to another compound. It's not relative to valsartan, right.
And you cannot just directly say, well, we see from association from dietary. It is not automatically claiming we have issue with valsartan.
Q. Yeah. My question is not that. My question is really about your experience and the work that you do.
You don't do that sort of work where you extrapolate results from

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one exposure setting to another exposure setting, correct?
A. Oh, we do. We do sometimes from clinical trial result. For example, in a cardiovascular trial, the patient usually is male patients, right. And especially in old age, very few female -- very few female patients involved.
So we actually very seriously need to know what the treatment effect the female patient would uptake, right.
So we actually utilize the entire study helping us to understand that extrapolation. But we try to do a good job, saying we establish a model for prediction for women, right with the baseline covariates.
And then we validate it. And then we apply this model with one dataset to another one.
So we do -- we do actually do this kind of work. But you have to be careful to convince people you can

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transport your model from one study to another one, right.
Q. So the model that you're talking about in the work that you've done would be looking at exposure in male patients and how that could be extrapolated to exposure in female patients, correct?
A. Yeah. That's a part of one study we did before.
Q. You're not talking about exposure in one setting and extrapolating to exposure in another setting, correct?
A. No, not that I recall.
Q. Okay. For Loh and Zheng, other than model fit, did you have any other criticisms of those studies?
A. Sir, this is just the two examples, you know, we can go over all the papers, publications that Dr. Madigan cited.
Most of the paper, just to follow the same -- like you're saying, the majority of paper, they didn't even

bother to evaluate how good the model is, right.

So those older publications, they sort of lack this kind of assessment and process. So it's not only for those two papers, by the way.

Q. Other than Loh -- you know, for Loh and Zheng, did you have any other specific criticisms of those studies?

A. Oh, other studies -- oh, these two particular studies that you're talking about?

Q. These two studies, any other criticisms of those two studies?

A. Well, I don't know they actually use -- you see, Counsel, I wanted to share with you, if you go back to the Loh covariate adjustment, right, you can come up how many covariates they make adjustment. If you have 11 or 12 covariates adjustment, for example, for sake of argument, you put age as adjustment, right, and the question is do you think age squared is also an

important adjustment. You say we don't know.

How about age cubed, do you need to make adjustment. Do you think actions among the 11 covariates will be included in the model?

You see, model is a simplified version of the truth. The true model is so complex. We actually try to approach the true model with a simplified model.

Now the question is can we actually assess your simplified model, actually close to the truth, right.

So you see, you can see the Loh and also Zheng papers, right. You say, well, I don't know, like we call kitchen sink, right. And do whatever the result are coming up, right. That's what people usually do.

You see, they say well, let's put everything in this disposal and see what happens. It's not a way to do business or scientific investigation.

If you want to use those papers as legal cases, you know, please do, but how in the world we can believe one informing a thing, I don't know how many people would believe it. That's my point.

Q. So your point is you believe that Loh and Zheng may have over adjusted the findings, included too many covariates or confounders that they adjusted for? Is that what you're saying?

A. No. Could be under. Who knows? Basically, I don't know what is the right adjustment. You need a validation set to tell me, yes, this is right amount of adjustment. You cannot adjust to put everything in the sink, say, listen, let's do it.

You know, people in the real world, they have hundreds and hundreds of covariates, right. They say using this machine, learning the process. Well, let's see what's going on. They end up

with a model. They say, well, okay, believe it or not, this is my model.

I said, hold a second, if you cannot validate this model, nobody is going to believe you.

So that's the trend this day, sir. You know, unfortunately the dietary papers are such older papers probably mostly right. They didn't even bother -- in the modern world if you don't have validation of the model, nobody will even believe you. If you read a medical journal, everything they're talking about modeling, they have the validation set, independent validation set, right.

So though you can see the trend, the people really want to have a valid scientific sort of conclusion from your study.

Q. There are many modern observational studies that are published that do not include a clear thorough model fitting assessment described in the

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studies, correct?
A. Well, if you find a paper in New England Journal of Medicine or JAMA, I would be very surprised, okay. But if you find it published in a mediocre journal, anybody can publish this space, as long as you pay a few thousand dollars, right, you can publish. A publication doesn't mean this is a valid argument, right. It's not credible.
Q. Okay. So let's take New England Journal of Medicine or JAMA.
You recognize that there are many modern observational studies that have been published in the New England Journal of Medicine or JAMA that do not include a clear thorough model fitting assessment described in the study, correct?
A. Well, give me example. In the past six months, what kind of paper are you talking about?
Q. How many examples do you want?

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A. Yeah? Well, the example --
Q. How many examples do you want to recognize that there are many modern observational studies that have been published in the New England Journal of Medicine or JAMA that do not include a clear thorough model fitting assessment described in the study, how many studies --
MR. MERRELL: Object to form.
BY MR. NIGH:
Q. -- do you want to prove that point?
A. Well, it doesn't matter. If you give me a couple of really high profile observational studies without validation, I will be very happy to write a letter to associate editor. I know those guys very well. I say how in the world you guys publish this junk paper, okay.
You tell me. You pick a couple of papers. I'm going to tell my

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friend, say you guys better do a better job.
Q. Okay. Taking a look at Page 12, Number 23 in your opinion. You say, "Moreover, for the papers in meta-analysis cited by Dr. Madigan, it is not clear if the authors for the individual papers in the meta-analysis had carefully checked the adequacy of the models utilized in the analysis. Without such analysis, the conclusion of the meta-analysis and inferences drawn by Dr. Madigan based on the meta-analysis would be invalid and inherently unreliable."
That is rarely done for any meta-analysis of observational studies, correct?
A. That's why we got so many meta-analysis papers floating around in this world, counsel. You know, how many do you believe is a result of meta-analysis? I think of very few.
Q. Can you name one

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meta-analysis of observational studies that has carefully checked the adequacy of the models of all the studies that were utilized in its analysis?
A. Well, you can check New England Journal of Medicine. We can go through tomorrow. We can get online to check all the recent New England Journal of Medicine -- meta-analysis New England Journal of Medicine published.
I'll tell you the truth, New England Journal of Medicine doesn't publish any meta-analysis papers anymore in the past two years anymore, because they don't believe in meta-analysis, right.
Then you say well, this is not fair. You say other journals publish meta-analysis. I say well, gee, you know, look at the high standard of the journal. They actually don't believe this meta-analysis anymore.
After they published the Vioxx meta-analysis everything -- no, I'm

sorry, it's for the GSK, Tanzeum, right, so-called antidiabetes drug, and they publish meta-analysis about maybe 12 years ago, maybe more than that. That was last paper.

New England Journal of Medicine published meta-analysis, they learned a bad experience from publish that paper.

You can tell me if The New England Journal of Medicine has published a meta-analysis in the past few years, I'll be very happy to share with my associate editor friend at New England Journal of Medicine. I say, gee, how come you guys change your policy.

Q. Can you name one meta-analysis of observational studies that has carefully checked the adequacy of the models of all the studies that were utilized in its analysis?

A. I don't know exactly there is one. You are a high standard lawyer. You don't want to go with those people,

what the majority say, hey, those guys are not very good. So if the majority of people are not very good, it's okay. But, sir, that's not okay, right.

You like to be in the small minority, you do a good job. You have a high standard. You actually set a good example for next generation, correct?

Instead of using -- say, hey, listen, nobody is doing this, so I don't have to do it. Why do we do that. If society goes what you are trying to do, we are in trouble. We cannot find truth anymore, right.

Why do you want to say majority guy didn't do it, so I didn't do it. But you know they are not correct. Why even bother to say I want to mingle with those guys.

Q. So is it your testimony that you cannot name one meta-analysis of observational studies that has carefully checked the adequacy of the models of all of the studies that were utilized in its

analysis?

A. Yeah, most meta-analysis I dealing with using clinical trial result, individual study. So in that case you don't have to make adjustment, because basically they are balanced, right, between the two groups comparatively.

So usually we don't worry about this so-called model checking, because there is no model.

But anything beyond that, you needed to worry about it. The individual study is a good study or not. You do a meta-analysis at this stage, you have to check. This study is a good paper or not a good paper, right? Everybody is doing now.

If it's not a really good paper, you don't include this paper or publication in your meta-analysis, right. That's the practice now.

Q. So do you agree that you cannot name one meta-analysis of observational studies that have carefully

checked the adequacy of the models of all the studies that were utilized in its analysis?

MR. MERRELL: Objection to form.

THE WITNESS: You're saying observational studies; is that correct?

BY MR. NIGH:

Q. Yes.

A. No, I don't -- I'm sitting here. I don't know. Maybe I can do some search afterwards and find out for you.

Q. It's not the state of the art for published meta-analyses of observational studies to look at each individual study that -- in the meta-analysis and check whether or not all of the studies described adequacy of the models utilized in the analysis, correct?

MR. MERRELL: Objection to form.

THE WITNESS: Well, sir, I

really don't understand. Why do you want to lower your standard?

I mean, you have a choice of being very high standard, right? Why do you want to say the majority don't do it, so that's okay and it's acceptable?

It's not acceptable.

You publish a lot of junk papers in this world, is really not helpful to the society.

BY MR. NIGH:

Q. Is it your belief that because New England -- you stated multiple times that New England Journal of Medicine no longer publishes meta-analyses.

Is it your belief that they are -- that you would give them -- that you ignore them or give them little to no weight?

A. Well, they -- I think they got a bad experience from this GSK Avandia study by cardiovascular people in

Cleveland Clinic, Steven Nissen. They got really hurt. And the people actually criticized that paper back and forth and left and right. So they feel so embarrassed.

So I still remember my old friend, Steve Largaucous, was associate editor, handled that paper for The New England Journal of Medicine. After it's published, I ask Steve, I said, "Steve, how in the world you publish this junk paper?" He said, "Well, I apologize. We didn't realize, you know, the guy used the wrong methodology."

Right. Now, they even used the clinical trial data, by the way. It's not observational study. But they used the wrong statistical method to combine in the meta-analysis, right.

So everybody jumping up and down. And this is a famous example.

Even Congress, you know, had a public hearing. It becomes a really interesting public sort of, like, news,

you know, in that days.

Anyway, I think New England Journal of Medicine really pissed. They are -- I'm not going to publish any paper in the future using meta-analysis.

Q. So is it your belief -- I understand what you're saying about New England Journal of Medicine. Is it your belief that meta-analyses have little to no weight and you would ignore them?

A. I don't know why -- I cannot speak for New England Journal of Medicine.

If you really wanted to know, I can introduce the editor of New England Journal of Medicine. He's a professor in our school.

Q. No, no. I want to make sure you understand my question. I'm not asking about New England Journal of Medicine. Throw that part out.

Is it your belief that meta-analyses have little to no weight and you would ignore them?

A. If they actually, each individual study, if like we are saying, is very good study, then you can combine information using the so-called well-conducted study, right, as a summary of the so-called group difference.

But if you combining, no matter what, the quality of the paper is not very high, and that's really hurting us. Even though you win this legal case, this won't help the society. Right.

Q. If a meta-analysis doesn't carefully check the adequacy of the models of every single study that are utilized in the meta-analysis, then you would give that meta-analysis little to no weight and you would ignore it, correct?

MR. MERRELL: Objection to form.

THE WITNESS: Yeah, I wouldn't take it seriously.

BY MR. NIGH:

Q. I'm sorry. You said, "Yeah,

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I wouldn't take it seriously," correct?
A. I won't, yeah. I won't take it.
Q. Let's take a look at Page 13 -- actually Number 12.
You can see it starts off with, "In their paper Hidajat, et al., stated." You can see that Number 24 is talking about Hidajat.
On Page 13, you see that, "Censoring" -- middle of the page where it talks about censoring competing events.
"Censoring competing events violates the assumption that censoring occurred at random and is independent from the risk of dying from the cause of death of interest, leading to a biased Kaplan-Meier estimator."
Do you see that?
A. Yes, sir.
Q. Is it your belief that the Hidajat study used a Kaplan-Meier estimator?

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A. No, sir. This is from their paper. It's not my language. I am quoting what they are saying.
Q. Yeah. What I'm asking you, is it your belief that the Kaplan-Meier -- that the Hidajat paper utilized a Kaplan-Meier estimator?
A. No, no, they tried to avoid using Kaplan-Meier. That's the sentence that you show to us. That's why they don't use Kaplan-Meier. They use cumulative incidence function. These are not my words.
Q. Please ex -- Hidajat used the method by Fine and Gray, correct?
A. Sorry, say it again.
Q. Hidajat used a method by Fine and Gray, correct?
A. Oh, yeah. Jason Fine was my student back in Harvard days. You know, he was my Ph.D. student. I know that paper very well.
Q. Please explain what the problem is with using the Fine and Gray

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method?
A. You want me to explain to you?
Q. Yes.
A. Okay. Do you want to go to the paper I cited, the Annals of Internal Medicine. I can take sweet time to explain to you. It's a beautiful paper we wrote.
Do you want to do that?
Q. Where is the paper that you write about the problems with the Fine and Gray method?
A. Go down to reference.
Q. I don't see a reference on this page. Is it on the next page?
A. Next -- yeah, the next paragraph, 25. We have JAMA-Cardiology, McCaw; New England Journal of Medicine, Annals of Internal Medicine.
Those are all papers saying Fine and Gray has a ratio for subdistribution function is not appropriate.

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You look at the journal we published. New England Journal of Medicine, Annals of Internal Medicine. JAMA-Cardiology. That's really the top -- really top clinical journals, right. It is so hard to get into those journals.
As a statistical argument, you can see it. They knew that it was such an important issue. That's why they publish. I'll be more than happy to go through this Internal Medicine paper with you. If you want to go on tomorrow, I'd be happy to spend all day with you.
And you are a smart guy. And towards the end of the day, I hope you would support what we are finding, right.
Q. I'm not asking you -- I'm not asking to go through the paper. I'm asking you to explain what the problem is with using the Fine and Gray paper. Can you not do that without going through the paper?

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A. Well, sir, if I say subdistribution function, do you understand what I'm talking about?
Q. Yes.
A. Well, do you understand what this guy is talking about, subdistribution function?
Q. If I'm -- you know, as the attorney, I'm the one who needs to ask you the questions.
So I'm asking you, can you explain what the problem is with the Fine and Gray method without utilizing the paper?
A. Okay. So let me try. Okay. I guess you don't understand the definition of subdistribution function.
So a patient died from cancer, right. And a patient could have died from other causes, cardiovascular events, right. So it's a noncancer death.
You have a typical signal illustration. You have two type of

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death. One is due to cancer. The other one is due to noncancer, right.
So this paper is interesting. We said, well, the mortality rate, the overall survival or death rate is 94 percent, is very, very high, almost everybody is dead, right, toward the end of the study.
We said, well, the majority of people, they died without a cancer cause. That means people died because of either cardiovascular event or because of kidney failure, whatever you define, right.
So you have two types -- kinds of death. If the guy says, well, gee, you know, if you guys died from noncancer, I have no idea if the guy survived, how long will it take for him to die from cancer, right.
This is what we call competing risk. Right. The two causes are competing with each other. You can observe either one, either die from

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cancer or die from cardiovascular, right.
So I said, well, gee, you know, how do we handle this? So instead of using Kaplan-Meier curve, we started to estimate the distribution of those guys.
And I said listen, Counsel, if the guy died from cardiovascular, the reason, right, the cause, what is the this guy's time to die from cancer.
I say, man, you know, this guy is already in heaven. I don't know. You know, the guy probably never died from cancer anymore, right. Who knows he didn't have it.
So that means if the guy died from noncancer, basically, we have no information about this patient died from cancer anymore.
Okay. So that's competing risk.
So if you define this cumulative incident curve, which is called subdistribution now because you

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have the majority of people, they didn't die from cancer.
Your distribution never reached one towards the end of the day. Otherwise the subdistribution function should be from zero to one.
So that's why we have subdistribution function. Okay.
Then you say what is the hazard ratio for this case. I say, wow, gee, well, that's interesting. I'm only interested in the death is due to the cancer. Right. I'm not interested in the death from the non-cancer.
I say, well, so how do you define the hazard ratio now?
I don't want to -- I don't know, sir -- this is not an insult at all.
Do you understand the definition of hazard ratio in general, even without a competing risk, do you understand the definition? Yes or no?
Otherwise I can explain to

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you hazard ratio without a competing risk first.

Q. I'm following your answer. But so far I have not heard your explanation of the problem in using the Fine and Gray method.

A. Yeah, so obviously you don't understand hazard ratio, right, without competing risk.

Hazard ratio is actually is intensity for mortality, force of the mortality. It's not a risk ratio. It's not an odds ratio.

So what is the hazard? Hazard means that a person -- and still, for example, six months right now, this guy is still alive.

I say, well, gee, you know, Counsel, what is the probability the guy still survive at six months, then suddenly drop dead next week? Okay.

And I actually figured out a standardized slope of intensity of this guy what's called hazard. So you go

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along with six months, 12 months, 18 months and et cetera. So you have a curve.

That curve is called hazard curve. What is hazard ratio? Hazard ratio means that if -- two groups, they have a two hazard function.

And I say what's the hazard ratio? You're assuming these two hazard function are proportional. That means the ratio of the two hazard function is constant over time. You're estimating that parameter. That's why you got the so-called .7, .75, the so-called hazard ratio. Right. Okay. That's for non-competing risk.

Then you have a -- there's a competing risk happening. You say, well, gee, you know, I'm only interested in hazard, dying from the cancer. Right.

I say okay, so what are you -- what are you talking about now? If a guy die from non-cancer, what are you going to do with the patient?

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I say, well, I'm going to put a limitation in my risk assess forever. Right.

Even the guy died from non-cancer, I said, well, in heaven, the guy is going to eventually develop a death of cancer.

Do you think this is a reasonable assumption? Of course not. Right.

That's what Jason Fine and Bob Gray's paper, they even themselves indicate it's an interpretation problem.

So we actually in the Internal Medicine explain to people, this is paper written for clinical people. You know, it's well written. I recommend it if you cannot falling asleep some night, to pick it up and read it.

And we explain to people, this is not logical the quantity you can use. Right.

And people didn't know how to do it. So in the Internal Medicine

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paper, we give alternative ways to help us to understand, instead of using hazard ratio, using something else, right.

So that's why people started picking up, oh, yeah, yeah, yeah, this is actually very good.

Is that okay with you now? Or you still don't understand?

Q. I still haven't heard you explain what the problem is with using the Fine and Gray method.

A. I told you. If the guy died from non-cancer, what is the hazard the guy is going to have a cancer death? Can you answer me? No, you can't, right?

Jason Fine actually put this guy in the risk assess when they computed the hazard. That's the problem.

Q. That's your --

A. I don't know if it's too complicated --

Q. That's your criticism of the Fine and -- have you -- do you feel like you've given the full answer on your --

what you believe to be the problem with using the Fine and Gray method?

A. Yeah, you know, this is such complex situation, sir. If you don't read my paper, even I spend 20 minutes with you, I don't think you can get it, right.

If you read my paper, just take ten minutes, you can understand the underlying formula. Okay. So, you know, I'd be happy to go through the paper quickly with you if you wanted to, if you really want to find out what's wrong with Jason Fine's estimate.

In fact, he wrote this paper asking me to be author. I told him, I say, Jason, this doesn't make sense. And I don't want to be co-author. So he said fine. Okay.

Q. Do you feel like you've answered my question on what is the problem with the Fine and Gray method?

A. Are you asking me?

Q. Yes.

A. I said it clearly, but you don't understand. I don't know what I can do.

I mean, I said the guy in heaven already, died from a cardiovascular event. And I said how are you computing this guy's hazard for cancer death?

Q. Okay. Let's take a look at the next page. Page 14, Number 26.

Next you have, "Based on the information available and the content of Dr. Madigan's report, we cannot use the results from diet or occupational studies to make an inference about the exposure effects for the population with valsartan. For example, from the meta-analysis by Song et al., regarding gastric cancer" --

A. I'm sorry. Mr. Nigh, could I stop here?

Q. You want to take a break?

A. Yeah. I'd like to take a break. And we're going to decide we like

to continue tonight or not. Is that all right with you?

Q. Sure. Yes.

MR. MERRELL: Is that all right, Mr. Nigh? We probably should confer. It's going pretty late.

THE VIDEOGRAPHER: I'm sorry. Are we going off the record? I'm sorry.

MR. NIGH: Definitely.

MR. MERRELL: Yes.

MR. NIGH: Let's go off the record.

THE VIDEOGRAPHER: The time right now is 5:37 p.m. We're off the record.

(Excused.)

(Deposition adjourned at approximately 5:37 p.m.)

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, LEE-JEN WEI, Ph.D., have the opportunity to read and sign the deposition transcript.

_____

MICHELLE L. GRAY,
A Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter and Notary Public
Dated: September 17, 2021

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Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, 1 - 401, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

LEE-JEN WEI, Ph.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

_____

Notary Public

LAWYER'S NOTES

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	:	MDL NO. 2875
	:	HON. ROBERT B. KUGLER
THIS DOCUMENT APPLIES TO ALL CASES	:	

- CONFIDENTIAL INFORMATION -
SUBJECT TO PROTECTIVE ORDER
VOLUME II

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September 15, 2021

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Continued videotaped remote deposition of LEE-JEN WEI, Ph.D., taken pursuant to notice, was held via Zoom Videoconference, beginning at 9:31 a.m., on the above date, before Michelle L. Gray, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

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I N D E X

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E X H I B I T S

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DEPOSITION SUPPORT INDEX

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Direction to Witness Not to Answer
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None.

Request for Production of Documents
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None.

Stipulations
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None.

Questions Marked
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None.

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THE VIDEOGRAPHER: We're now on the record. My name is Judy Diaz. I am a legal videographer for Golkow Litigation Services.

Today's date is September 15, 2021, and the time is 9:31 a.m.

This is a continuation of the deponent Lee-Jen Wei, Ph.D.

All counsel will be noted on the stenographic record. The court reporter is Michelle Gray. The deponent is already under oath.

You may begin, Counsel.

- - -

... LEE-JEN WEI, Ph.D., having been previously sworn, was examined and testified as follows:

- - -

CONTINUED EXAMINATION

- - -

BY MR. NIGH:

Q. Okay. Let's go ahead and pull up LP-1569. This will be marked as Exhibit 14.

(Document marked for identification as Exhibit Wei-14.)

MR. NIGH: And let's go ahead and turn to Page 131.

BY MR. NIGH:

Q. Doctor, this is the ASA statement on statistical significance in P-values in 2016 that you spoke about multiple times in your deposition yesterday, correct?

A. Yes, sir.

Q. Okay. Let's take a look at the -- well, first let's take a look at what is a P-value. It says, "Informally a P-value is the probability under a specified statistical model that a statistical summary of the data (example, the summary mean difference between two compared groups) would be equal to or more extreme than its observed value."

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Do you agree with that statement?
A. Yes, sir.
Q. Okay. Under principles. Now, these principles, these are the -- these are the principles of the statement that you were discussing yesterday, correct?
A. You want me to read it? What is your question, sir?
Q. No. I said these principles, these are the principles of the ASA statement that you were discussing yesterday, correct?
A. Can I read it?
Q. I'm sorry?
A. Can I read it?
Q. Principles. Yes, we're going to go through them.
A. Yeah. Please read for me, or I can read it myself. Which way you prefer before I answer the question?
Q. Oh, I see. But first is, you feel like you need to read through

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the six principles to know whether or not the word "principles" underneath ASA statement refers to the principles?
A. Yeah. I see the boldfaced underneath, yes.
Q. Okay. So first principle, "P-values can indicate how incompatible the data are with the specified statistical model."
Do you agree with that principle from the ASA statement?
A. Yeah. For our case, essentially you are assuming there's no association. That's the model you're talking about.
Q. Number two --
A. So I --
Q. Oh, sorry, I didn't know you weren't done.
A. No, that's okay. Do you want me to read the fine lines or that's not relevant?
Q. The second one is, Number 2.
MR. NIGH: Let's go ahead

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and pull that one up.
THE WITNESS: I'm sorry. You didn't answer my question. I said underneath 1, there is details. Do we want to go over or you don't want me to go over?
BY MR. NIGH:
Q. Okay. I think I addressed this earlier, that the attorneys ask the questions. So we don't answer the questions.
So no, I don't need to go through the fine line below unless you feel like you need to, to answer the question.
So the second one is, "P-values do not measure the probability" --
A. I'm sorry to interrupt you. I'd like to read it.
Q. What do you want to read?
A. Read that Number 1 underneath the title.
Q. Okay. We can go off the

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record and you can read this document if you want to.
A. Okay.
Q. Go ahead.
THE VIDEOGRAPHER: The time right now -- the time right now is 9:35 a.m. We're off the record.
(Whereupon a discussion was held off the record.)
THE VIDEOGRAPHER: The time right now is 9:38 a.m. We're back on the record.
MR. NIGH: Let's go ahead and put LP-1569 up.
BY MR. NIGH:
Q. I want to draw your attention to Number 3. This is the one that you cited in your report.
It says, "Scientific conclusions and business or policy decisions should not be based only on whether a P-value passes a specific threshold."
Do you see that?

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A. Yes, sir.
Q. Now, that statement doesn't say not to use the words "statistically significant" or to stop looking at P-values, correct? It says, "Not based only on whether a P-value passes a specific threshold." Correct?
A. I'm sorry. I missed your first phrase related to statistical significance, could you say it again, please?
Q. Let me break this down. That statement uses the word "not be based only."
MR. NIGH: Can we highlight the word "only."
BY MR. NIGH:
Q. Do you see that, the word "only"?
A. Yes, sir.
Q. This doesn't say to stop reporting P-values altogether, correct?
A. I don't understand what you're talking about, sir. You highlight

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"only on." I agree with that phrase. What else are you talking about? What are you referring to?
Q. The sentence, "Scientific conclusions and business or policy decisions should not be based only on whether a P-value passes a specific threshold."
This principle doesn't state to stop reporting or relying on P-values altogether, correct?
MR. MERRELL: Objection to form. The document speaks for itself.
THE WITNESS: Well, everybody agree there's a P-value is one of the components. I didn't say you are not going to reporting anything in my report. You can report anything that you wanted to. I said this is not only thing you can use. That's exactly I mentioned what -- Number 3.

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BY MR. NIGH:
Q. Right. And this statement doesn't say to stop using the word "statistically significant" either, correct?
MR. MERRELL: Objection to form. Document speaks for itself.
THE WITNESS: Wait a second, sir.
MR. NIGH: "The document speaks for itself" is an improper objection. Please keep it to objection to form.
THE WITNESS: Look at "The use is widespread," on the bottom. Statistical significance. Look at it on the bottom.
MR. NIGH: Yeah, let's highlight that.
THE WITNESS: Sorry?
BY MR. NIGH:
Q. Let's highlight that.
A. Yeah.
Q. And the next statement says,

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"The widespread use of 'statistical significance' as a license for making a claim of a scientific finding or implied truth leads to considerable distortion of the scientific process."
It doesn't say to stop using the word "statistical significance" as a descriptor, does it?
A. Sir, you can use anything you wanted to. And how did you actually interpret? That's a different method, right. ASA suggests that don't use this one. You guys say, I want to use it. You go ahead and use it.
This is free world. Nobody is going to stop you to not using it, right.
Q. Well --
A. I didn't say you're --
Q. Sorry, I didn't know you weren't done.
A. -- not allowed to use it. Sorry?
Q. Sorry. I didn't know you

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weren't done. Go ahead.
A. I'm trying to say, sir, the last sentence exactly reflecting ASA saying, don't use statistical significance, especially using P less than .05 as a license to make a decision. Right.
That's exactly what we want the people, including you, sir, to understand. Life is not so simple. We cannot use black and white. Basically, using P less than .05. That's the message we're sending to outside world.
If you don't want to listen, that's okay. You have any freedom to use it. Right. Nobody stop you using it. We just say this is not a valid argument based on ASA statement. That's it.
Q. All right. Can you listen to my question.
My question was, the ASA statement does not say to stop using the word "statistical significance" as a descriptor only, does it?

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A. You can use it. They didn't say you cannot use it. But they said it's not appropriate to use it. That's what they said.
Q. They said --
A. Nobody is going to -- sorry.
Q. They said not to use it as a license for making a claim of a scientific finding or implied truth. Don't use it for that purpose. But they did not say to stop using it as a descriptor, correct?
A. That's not my -- that's not my interpretation, sir. You can interpret your way. I can interpret my way. All right.
Q. So you believe, as you read these words, that the ASA says to stop using the word "statistical significance" in studies. That's your interpretation?
A. Yes, sir.
Q. Okay. Do you recognize that even between the date of the publication of this study -- I mean, of this

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statement, in 2016 and today's date, the vast majority of observational studies that are published in journals continue to use the word "statistical significance"? Agree or disagree?
MR. MERRELL: Objection to form.
THE WITNESS: Unfortunately, sir, people don't listen.
BY MR. NIGH:
Q. And even --
A. They just --
Q. Sorry. I didn't know you weren't done.
A. People should be getting smarter and understand how to translate the data to be interpretable.
And ASA is doing their job. I too tell the outside world, don't use this word literally saying black and white decision. If people wanted to use it, that's their freedom. And being a scientist, a statistician, being a good lawyer like yourself, we should take

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advice from ASA instead of totally ignore it. Right.
Other people, you know, they misuse it for many, many years. Now they are saying please don't use it. People have a bad habit. Very difficult to change the habit. And then they still use it.
So what are you going to do? As a reader, as myself as a professor in biostatistics, I say please, I'm going to helping ASA to spread the word, please don't use this black and white simple rule to make a decision. Okay.
You can argue any way you want to do and say most of the people still use it. I say, well, gee, you know, why people still use it? Can we actually educate the people a little bit more, helping society? They say oh, no, no, I don't care, as long as everybody -- most of the people use it. I will use it.
Is that a right way to do

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business, sir, to be a good citizen of the society? It's not only for winning the case or losing the case, right. We actually take this opportunity, actually find the truth, right, instead of just using everybody who misuse the language to helping your case. I'm not so sure that's good for society. Do you agree?

Q. So you would agree that the vast majority of observational studies continue to use the descriptor "statistical significance"?

A. Yeah. Dr. Madigan didn't have to. He is a distinguished statistician. He agreed with ASA statements in his deposition.

Q. Well, Dr. Madigan in his report, at no point does he ever make the claim of a scientific finding when he uses the word "statistical significance." He never actually makes a claim of scientific finding or implied truth in his report when he uses those words, correct?

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A. I don't know, sir. I have to read his report. If you say so, I feel sorry for him.

Q. I'm sorry. What?

A. If he said his finding is not scientifically findings, I really feel sorry for him. That's what I'm saying.

Q. You mean if when he uses the word "statistical significance," if he were to say that he's not using that as a license for making a claim of a scientific finding or implied truth, you would feel sorry for him?

A. Yes.

Q. Why?

A. Because some -- Dr. Madigan, being a distinguished statistician, if any statistical analysis cannot be interpreted scientific findings, I say why -- why in the world are we sitting here, right? You just play number games. And your result cannot be even applied to the real-world situation.

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I'm really surprised, sir, if he really say so. I'm really interested to pick up a sentence that he claim in his report, and I'm going to send it to ASA and say, hey, listen, man, you know, this is a distinguished professor saying such things. What do you guys think?

Q. I'm sorry. What have you stated that you're going to send to ASA?

A. If what you say is really what Dr. Madigan said in his report -- by the way, his report will be in the public domain anyway eventually, right? We can easily just send this newsletter or whatever to ASA, the publication, and say, listen, you guys make so much effort talking about statistical analysis, helping people, improve this society scientifically.

We have this distinguished statistician, a professor at Northeastern University, and say, well, anything I did here cannot be actually extrapolated to

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scientific findings. I said, my goodness, why in the world are you wasting your time to do the data analysis which cannot be even used for a scientific argument? If that's exactly I understand what you're saying, I'm really sorry to hear that, sir.

Q. You might be misunderstanding what I'm saying.

When he uses the word "statistical significance," he at no point in his report uses them as a license for making a claim of scientific finding or implied truth, correct?

MR. MERRELL: Objection to form.

BY MR. NIGH:

Q. You've reviewed his report.

A. What? Are you done?

Q. You reviewed his report. Do you remember him saying after -- that the study reported statistical significance, that he was interpreting that -- or that he was using that as a license for making

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a claim of a scientific finding or implied truth?
A. Did he use the exact words, a license, no? Right. But if you see his conclusion -- did you see that? Everything that he did, using P less than .05, and then claim there is a risk of cancer. Right.
That's exactly what you said. I don't understand what you're talking about, sir. I'm really sorry.
Q. At any point, as you reviewed his report, do you recall him ever attaching the word "statistical significance" and then use those as a license for making a claim of a statistical -- a scientific finding or implied truth as opposed to just using that as a descriptor, pulled from the study itself?
MR. MERRELL: Objection to form.
THE WITNESS: You are asking me did he say anything like

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exactly like you're saying as a license for making a claim of scientific findings in his report?
Is that what you're asking me?
BY MR. NIGH:
Q. My question, as you reviewed Dr. Madigan's report, do you recall him ever attaching the word "statistical significance" and then use that as a license for making a claim of a scientific finding or implied truth as opposed to just using that as a descriptor pulled from the study itself?
A. Boy, I tell you what, sir. If you actually exactly -- Dr. Madigan saying just like a descriptor, instead of an inference, we are in trouble. That means what you're saying, just descriptor. There's no way you can make an inference saying the threshold -- whatever the number you used yesterday. I'm sorry. I don't know the value. He said past this value of a contamination, you are in trouble.

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I said, well, my goodness, is that a scientific finding, what he claim? You're saying, oh, this has nothing to do with it because he just use P-value as a descriptor.
I say, sir, what do you mean by descriptor. Descriptor means it's nothing. Just describe the situation. I say, well, how do we use your descriptor? Make a decision. I say, I don't use it. I don't use a P-value to make a decision.
Come on. I mean, sir, that's really strange, right? He use older way. He uses P less than .05, decide black and white. Now you're saying no, no, no, he didn't do that. I really got confused now, sir.
Q. Where do you think in his report that he used it in black and white or as a line in the sand or as a threshold? Those words show up anywhere in his report, correct?
A. No. I'm saying he used statistical significance all the time.

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He translate his words, statistical significance mean yes, there is an increase of cancer risk. That's the implication, sir.
Q. If you actually look at those studies when he would use the word "statistical significance" to say -- to see if the study itself, he used the word "statistical significance"?
A. I'm sorry. I don't catch what you're saying, sir.
Q. Did you actually pull up the studies where he used the words "statistical significance" to see if that descriptor was also in those studies, statistical significance?
A. Did you say -- did he say that he used a P-value as a descriptor, sir, in his report? Help me out. Did he say anything?
Q. My question here is, did you actually pull up the studies where he used the word "statistical significance" to see if those other studies also used

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those same exact words, "statistical significance"?
A. What do you mean by he? Dr. Madigan?
Q. Dr. Madigan, yes.
Let me ask that question again.
Did you actually pull up the studies yourself where Dr. Madigan used the word "statistical significance" to where you yourself could see if those studies also used those same exact words, "statistical significance"?
A. Sir, looking at Table 1, Dr. Madigan's report, okay.
Q. Yes.
A. There is a column for "SS?" That's a statistical significance or not, right?
Q. That doesn't mean sample size?
A. Listen -- listen to me. You have to listen to me first, sir.
Q. I'm sorry. I thought you

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were done.
A. I'm really polite to you. Every time I wait until you finish. You have to give me the right to finish my thing, right. Otherwise I'm going nowhere here, sir.
Q. Sir, you pause after some of your sentences, so I believe that you're done. But yes, I will try to wait just in the same way that I've asked you to wait until I'm done.
A. So you're looking at Table 1 in the column called "SS?" Look at this underneath the footnote. What he say? Statistical significance. That's SS.
He actually saying the Q1 against Q2 against Q3, which one is the statistical significance.
If this only descriptor, why he make this every paper, every publication he cited, he says this one is statistical significance or not.
Did I answer your question, sir?

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Q. Let's go ahead and pull up that table.
MR. NIGH: LP-1588 -- or 1558. This is Dr. Madigan's report. We'll look at Table 1.
BY MR. NIGH:
Q. Let's go ahead -- now, yesterday when I asked you what SS stood for, you guessed that it may stand for sample size. Do you remember that?
A. No. I didn't say anything. I said because I -- I have to read the footnote. And I was in a hurry. I didn't read the footnote.
Then I look at it last night. I say, oh, that means statistical significance. If the sample size, this is not issue, right?
Q. I'm sorry. You believe that you need to see the footnote to be able to tell that means statistical significance?
A. Otherwise, I don't understand the abbreviation SS, question

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mark, sir.
Q. Okay. When it comes right after effect size?
A. I'm sorry, sir?
Q. When it comes right after effect size, you wouldn't know what "SS?" means without the footnote?
A. This is not a standard of abbreviation for "SS?" No one use this one.
Q. Okay. But now today you know that SS stands for statistical significance?
A. Yeah, yeah. I read the footnote. Look at the footnote. If you can pull up a little bit.
Q. Sure.
A. You can see the footnote.
Q. You feel like you would need the footnote in order to know that "SS?" stands for statistical significance? Is that what you're saying?
A. Of course. Of course. Otherwise I wouldn't understand what SS

means.
Q. Couldn't you just pull the study itself, like you could have -- if you had looked at De Stefani -- let's highlight De Stefani. If you had looked at De Stefani and you had seen the results there, couldn't you have seen that the Y is a yes?
A. What is your question, sir?
Q. If you had pulled up De Stefani, couldn't you have seen that it was statistically significant, a yes, if you had looked at the dietary study and compared it to this table?
A. I don't know what language they use in the paper. We have to read again, right, to see what they say -- if they say anything about statistical significance.
According to Table 1, and Dr. Madigan say Y, as a star. Right. If you look down the bottom, what the star means, right. That's it from his table.
Q. Couldn't you have looked --

sorry, I didn't mean to interrupt you. Go ahead.
A. If you want to go back to the paper, we'll sit and read it one by one to see who actually uses statistical significance, the word, right. And Dr. Madigan just translate or transport that statistically significant or not in his Table 1. That would be fine.
But I really don't understand your question. You said go back to the paper. You didn't say anything. I say, well, we can read the paper to see what kind of language did he use.
Q. So if I understand your testimony correctly, if the study used the word "statistical significance" and Dr. Madigan put that in his report, that would be fine, in your testimony, correct?
MR. MERRELL: Objection to form.
THE WITNESS: I don't

understand, sir. What do you mean by fine?
BY MR. NIGH:
Q. You just said -- sorry, go ahead.
A. If he copy this one, then he just reporting what the paper saying, right, in the table "SS?"
That's my interpretation. I don't know in the paper itself has clearly state their result are statistically significant or not. We don't remember. I don't remember this. You have to go back to check what language did he use.
Q. So your task was to review Dr. Madigan's report and write your own report. And when you testified yesterday, you didn't know that SS stood for statistical significance in his table, even though you had the ability to review all his footnotes and the table for at least two months before that deposition yesterday, correct?

MR. MERRELL: Objection to form.
THE WITNESS: Correct.
BY MR. NIGH:
Q. Have you gone through the studies, De Stefani, to see if it actually uses the words "statistically significant"?
A. You asked me again, sir. We can go back one by one these publications. Right. We can see what language they use in the papers.
Q. Yeah. My question is not for us to go back one by one. You've had two months to look at these dietary studies.
What I want to ask you is your understanding of the study now, not going through them one by one. Do you recall if De Stefani uses the terminology "statistical significance"?
A. You are testing my memory, sir. How many papers you list on the Table 1?

Q. Is your answer no?
A. I cannot answer your question until I refresh my memory reading the papers, sir.
Q. Fair enough. How about Pobel?
MR. NIGH: Let's highlight that one.
BY MR. NIGH:
Q. Do you recall if Pobel uses the terminology in that dietary study that its findings were statistically significant?
A. Again, sir, we need to go back to read the paper.
Q. So you can't answer that question without going back and reading the paper, correct?
A. Yeah, I don't want to test my memory, sir.
Q. How about La Vecchia? La Vecchia. Do you recall if the La Vecchia study shows that its findings were statistically significant or states that

its findings were statistically significant?
A. I don't recall.
Q. How about Larsson? Do you recall if Larsson states that its findings were statistically significant?
A. No, sir.
Q. How about Zheng. Let's highlight Zheng down under pancreatic. The second one. Do you recall if Zheng states that its findings for NDEA were statistically significant?
A. So let me make sure that you exactly asked me. You say, do I remember in this paper the authors use the words "statistical significance" in the paper, right? That's what you're asking me, correct?
Q. Yes, yes.
A. So I don't -- sir, with all due respect, right, I don't remember for each paper. So many papers I reviewed in this case, right. You don't expect me to remember every word in the paper, right?

I have less capability to remember everything they said in the paper. That's not fair.
If you have time, we can go through this paper, say who has used statistical significance, who did not. That's fair, right? But instead you ask me --
Q. I'm being fair with my -- go ahead.
A. You're asking me repeatedly, do you remember this so and so. I already answer your question. In general, I don't remember exactly, right.
But, try to be -- find out the truth, we should go back to read the papers. But you said you don't want me to go back to the papers.
Now, how in the world do you expect me to answer your question?
Q. My question is -- yet again, I'm not asking you to remember every single word in the study. I'm asking you simply for Zheng. Do you recall that for

pancreatic, that Zheng described its findings for NDEA as statistically significant? Yes or no?
A. I don't recall, sir.
Q. De Stefani.
MR. NIGH: Let's highlight De Stefani.
BY MR. NIGH:
Q. Do you recall that De Stefani described their findings as statistically significant?
A. I don't recall, sir.
Q. Goodman, both for males and females, do you recall that Goodman described their findings as statistically significant?
A. No, sir.
Q. Colorectal. Knekt, do you recall that the authors described their findings as statistically significant?
A. No, sir.
Q. Loh, for rectal, do you recall that they described their findings -- do you recall whether they

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described their findings as statistically significant?
A. No, sir.
Q. Zhu, do you recall whether they described their findings as statistically significant?
A. No, sir.
Q. And I missed one up there. Keszei, for -- do you recall that Keszei described their findings -- do you recall whether Keszei described their findings as statistically significant?
A. I don't remember.
Q. For all the ones that have no, an N, the ones that are not highlighted, do you recall whether any of those studies described their findings as not statistically significant?
A. I don't remember this.
Q. So out of the -- every single one of these studies, you don't recall whether any of them used the find -- words or findings of describing their findings -- well, strike that.

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So for every one of these studies listed on Table 1, you don't recall whether any of these studies used the words "statistically significant" or "not statistically significant," correct?
A. Sir, if the paper did not even mention the word "statistical significance," however Dr. Madigan in his Table 1 started using the word "statistical significance," I think Dr. Madigan overly used word "statistical significance" in this Table 1.
Q. Well, I understand that.
I'm asking you the other question. So for every one of these studies listed on Table 1, you don't recall whether any of these studies used the words "statistically significant" or "not statistically significant," correct?
A. Yeah, I wish I can read the paper, if you allow me.
Q. My question is, you don't recall whether any of these studies use the words "statistically significant" or

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"not statistically significant," correct?
A. Yes, sir.
Q. So as you sit here today, you wouldn't be able to know for any of these studies whether or not Dr. Madigan overly used the word "statistically significant" in this table, correct?
A. No, he did. He actually -- in this -- also in reporting statistical significance, this words that he used here, that means it's overly used.
Q. How do you know that none of the authors -- or that any of the authors didn't use the word "statistically significant"? We just went through every single study, and you couldn't tell me a single one as to whether or not they use the word "statistically significant," correct?
A. Sir, it doesn't really matter those guys did use or did not use. Even if everybody on the list, right, everybody use the "statistical significance" in their papers,

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Dr. Madigan should be smart enough to not just copy those words in Table 1, because he is a prominent statistician. He agrees with the ASA statement. Okay. So either way he overly used the word "statistically significance."
Q. So previously you told me that if he had just used the same words the study authors had used he was fine. Now you are changing your testimony to tell me because he is a prominent statistician, he should not be copying the words that the study authors used, correct?
MR. MERRELL: Objection to form.
THE WITNESS: Sir, you misunderstood what I'm saying. I said if the paper is saying statistical significance, he just literally copied, right, the words into table.
Operationally that's correct, right. He actually used

this word from the authors, right.
But if the authors didn't use it, he used it, then, wow, gee, you know, you are smart enough, you should not use it, right?
But you're saying, well, everybody use this word. I say, well, you're also smart enough. You shouldn't follow -- you should not follow those guys, right. You should not repeating the so-called statistical significance because you know very well those words are not appropriate, right.

BY MR. NIGH:

Q. Okay. My question is, do you believe it's fine for him to have copied the word "statistically significant" if the authors used those words as well?

MR. MERRELL: Objection to form.

THE WITNESS: I'm saying he

is operationally correct citing the authors' words, "statistically significant." Operationally, he's correct.
But should he repeat it, what the author is saying? I say he should not.

BY MR. NIGH:

Q. Okay. So it's your testimony that it would be operationally correct, but you believe that it would be a flaw, even if it's operationally correct to copy the words that the authors used, "statistical significance" or "not statistically significant." Is that your testimony?

A. What I'm trying to say, sir, operationally, if he copy what these authors saying, it's a correct way to copy.
But the responsibility to be a prominent statistician, he should not picking up something he does not believe. He actually agrees with ASA statement.

If he agrees, why should he even recite those SS from other authors, right? He should avoid.

Q. Okay. Understanding his responsibility to be a prominent statistician, is it your testimony then that he should not copy the words "statistically significant" if the journal authors used those words themselves?

MR. MERRELL: Objection to form.

THE WITNESS: I don't think that you actually understand what I'm saying, sir.

BY MR. NIGH:

Q. I don't --

A. I'm saying he can copy -- he can copy anything he wants to. But he should make very clear, those statistical significance does not mean we make a black and white decision, right. This Table 1 give people wrong impression, saying statistical significance plays a

vital role to decide this study is positive or neutral or negative. Right.
That's what I'm trying to say. Being a distinguished statistician, we should be better than those guys, right. We should educate the society. What is the most appropriate way to communicate with the society, right?

Q. Okay. So is it your testimony now that he can copy the words "statistical significance" or put a no or yes in a table that has a column "SS?" as long as he has a disclaimer that states -- that makes it clear that statistical significance does not mean we make a black and white decision. Is that your testimony?

A. I wish he did in his report, in helping us clarify this misused or overly used statistical significance, this terminology.

Q. So you wish, in his report, that he had a disclaimer that states statistical significance does not mean we

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make a black and white decision. Is that your testimony?
A. Yes, sir. I would respect him very much if he say so in his report.
MR. NIGH: Let's go back to the ASA. LP-1569.
BY MR. NIGH:
Q. Do you remember yesterday when you told me that The New England Journal of Medicine stopped reporting on P-values?
A. New England Journal of Medicine issued a recent guideline for statistical analysis. It is saying for primary endpoint for a single study, if you have pre-specified value of for -- a positive rate -- you know, sometimes people use .05, .01, .1, you know, whatever you decide in the beginning, in the design of the study, you are allowed to report the P-value for that primary endpoint.
And after that, only thing they say you can provide, like you said

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yesterday, is confidence interval. And confidence interval for all other secondary endpoints, and the confidence interval actually provides you more than just P-value.
Like you said, sir, very well yesterday, you can use 95 percent confidence interval to make a black and white decision. But I believe New England Journal of Medicine really wanted people to understand confidence interval is more useful, provide more information about so-called clinically significance, right, of your findings. That's my understanding.
Q. So the New England -- your statement is The New England Journal of Medicine still allows to report the P-value for the primary endpoint, correct?
A. With confidence interval. They actually want people to use more confidence intervals these days than P-value.

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Q. The vast majority of observational studies, you would agree, even going back 20, 30 years ago, report both the confidence interval and P-values, correct?
A. Some of -- some actually do not have it. Mostly they are reporting both.
Q. Do you believe there is a single dietary study that Madigan listed on his table that doesn't also report the confidence interval?
A. I don't recall, sir.
Q. Do you believe that there's any incident where Hidajat doesn't report the confidence interval?
A. I don't recall, sir.
Q. Let's take a look at other approaches, on the next page.
And you have -- I think you have a printed out copy in front of you.
So other approaches. Now, Number 4, other approaches, these are not part of the ASA statement principles,

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correct? That was Number 3.
A. I'm sorry, sir. What is your question?
Q. I said these other approaches, these are not part of the ASA statement principles. That was Number 3, correct?
A. Yes, sir.
Q. This is providing alternatives, correct?
A. Yeah, that's the other approaches, yes, sir.
Q. And it says, "In view of the prevalent misuses of and misconceptions concerning P-values, some statisticians prefer to supplement or even replace P-values with other approaches. These include methods that emphasize estimation over testing, such as confidence, credibility, or prediction intervals."
Do you see that?
A. Yes, sir.
Q. Now, it looks as if they are discussing other approaches. You can use

the confidence interval -- that's another approach -- prediction interval or credibility. But they -- this does not say or give direction to stop using P-values, correct?

A. ASA is not law enforcement agency. They cannot put you in jail if you use a P-value. In scientific society, everything they want to do is helping the society to understand the underlying cause, like this case, right.

And if you read it, sir, if you read this first paragraph you highlighted, they emphasize estimation.

What does that mean? That means that effect size is more important than the P-value. That's exactly what I said yesterday to you, sir. We need more information just than P less than .05.

Q. Right. This is highlighted under other approaches, not one of the six principles, correct?

A. Sir, I -- again, they have a principle ask that don't use the P-value

only. Then they say there are some alternative proposals, right.

ASA is not in a position to tell us you have to do A, not B, right. They give you other alternatives. This is -- everybody scratch their head to say what is the best way to translate data analysis and results in the real-world.

And, you know, people -- people don't listen. That's fine with us. We just say, look, if you don't listen, we just don't take your study serious.

Q. Right. The ASA has not given the position to recommend stop using P-values, correct?

A. They cannot stop you, sir. This not right language in the society, scientific society, right.

Q. The ASA hasn't given the recommendation to discontinue using P-values in studies, correct?

MR. MERRELL: Objection to form.

THE WITNESS: Sir, listen, this is go nowhere. I'm trying to say that ASA is not a legal entity, right. They cannot tell you how to do things. They cannot say stop using. Right. They just say if you -- if you want to use a P-value, you need something else, right. Help us.

BY MR. NIGH:

Q. Is your answer that you agree with me that the ASA hasn't given the recommendation to discontinue using P-values in studies?

A. Again, sir, ASA is not law enforcement agency. They cannot tell you stop using P-values, right. For example, you say, well, it's like stop stealing groceries, supermarket. Is okay, not okay, right.

I mean, the ASA saying please don't. Don't shoplifting in the supermarket.

But if you guys say, did ASA

say that you cannot do it?

I said, well, that's not my problem. If you want to do it, that's your problem, right.

But they just tell you that you should not do it, but they cannot say please don't use it. Stop doing it.

Q. Okay. Is it your --

A. You know -- sorry.

Q. Is it your testimony that the ASA has stated, "Please stop using P-values in the studies"?

A. No. They cannot do that, sir. They cannot issue that statement. Even your legal profession, you tell people how to do things. Like your firm, if you have a position paper published from your firm, you say "People stop doing X, Y, and Z." You know, people just ignore you, right, because they say if I do it, what is the consequence? There is no consequence, right. There's no penalty.

It's a matter of fact to

say, look, if you do it, it's a free world, you go ahead, do it. But how much I would trust your study now, that depend on me now. It depend on the society now, right.

Q. Did you read that the majority of the statisticians who sat during this process in this panel recommended that we continue to report the P-values in the studies?

MR. MERRELL: Object to form.

THE WITNESS: Most statistician, everybody -- almost everyone, including Dr. Madigan, agree with ASA statement, right.

If Dr. Madigan had a strong objection to what ASA is saying in this document, he could, as a member of the society, write a strong protest letter, right, saying, "ASA, you mislead us, you should not telling us not using P-values." Right.

Obviously, Dr. Madigan agree with us. He said we need more information, more than just, like, P less than .05.

He agree.

BY MR. NIGH:

Q. That wasn't my --

A. So he agreed -- sorry.

Q. Sorry. Go ahead. I didn't know you weren't done.

A. No, I'm sorry. I'm just trying to say, if majority of people, statisticians, all agree that these are the principle, then why we don't practice?

Why Dr. Madigan does not practice ASA statement issued in 2016. Now this is 2021. Five years.

And again, I know Dr. Madigan is a well known statistician. If he doesn't want to use this, changing his habit, how in the world he can take a next generation of statisticians, say, guys, we should make a better way to make

a decision.

Why is he still using the old-fashioned way using P less than .05? That's what gets me.

I said, well, you are provost in Northeastern University. It is a very prestigious, very powerful influential position. If he can't help society, he won't write his report solely based on statistical significance which ASA encourage us to do it.

In my report, I use a really milder word. I say ASA discourage using this P less than .05. I didn't say ASA asked us to stop using it.

Q. Okay. I'm going to ask this again because that was a very long answer, and nowhere in my question did I ask anything about Dr. Madigan. So I'm going to start the question now.

Did you read anywhere that the majority of the statisticians who sat during this process on this panel where they were coming up with the ASA

statement on P-values, that the majority of the statisticians recommended that we continue to report the P-values in the studies?

MR. MERRELL: Objection to form.

THE WITNESS: I don't know where -- you are saying panel. Which panel are you talking about?

BY MR. NIGH:

Q. Did you read that the majority of the statisticians who helped develop this ASA statement continued to recommend that we continue to report the P-values in the studies?

A. Well, you can report a P-value, but you should use other information to make a decision, right. You cannot use a P-value just simply a descriptor. And you say, well, what do you mean by descriptor?

Statistically speaking, descriptor is a very weak -- a very mild row. Right. There's nothing to do with

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mixed inference.
You say, well, you know, Dr. Madigan just use a P-value as a descriptor. No harm done.
I say wait a second, he actually used this in decisionmaking. Claimed this value was significant or not, just based on P less than .05. I said, well, this is not a simply a descriptor anymore.
So I said to you, sir, the majority of people, including me, I said well, fine, you shouldn't use a P-value if you're reporting. But you should do more than that, right, to make a decision.
Q. Did you read that the majority of statisticians who weighed in on this ASA statement continued to recommend that we report P-values -- that we continue to report P-values in published studies?
A. I don't know where you got this information from. But I agree with

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the majority of statisticians. You can report the P-values.
Q. Okay. Let's go ahead and take a look at your report.
MR. NIGH: This is LP-1557.
BY MR. NIGH:
Q. And I want to take a look at your reliance list at the very back of the report.
At the very back of this, there's a miscellaneous.
Now, first off -- actually, if we go to the very beginning. Materials considered.
Do you see that?
MR. NIGH: Let's blow this up.
MR. MERRELL: I have a hardcopy. Is it all right if I hand it to the witness?
MR. NIGH: Absolutely.
BY MR. NIGH:
Q. Do you see here where it says, "Dr. Wei List of Materials

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Considered"?
Do you see that?
A. Yes, sir.
Q. And then it first shows the master personal -- amended master personal injury complaint.
Did you review that complaint?
A. Speaking of Number 1, right, you're talking about?
Q. The very first one, yes.
A. Yes.
Q. It next says, "Master medical monitoring complaint."
Did you review that complaint?
A. I glanced over it. I don't remember exactly the content anymore.
Q. Next it says, "Master economic monitoring complaint."
Did you review that complaint?
A. I did a glance over.
Q. Next it says,

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"Confidentiality and protective order."
Did you review that?
A. Yes. I glanced over.
Q. Is it your understanding that the materials that have been provided and submitted are under confidentiality and protective order?
A. You ask me?
Q. Yes.
A. Okay. Yes.
Q. Do you believe that includes the expert reports that have been submitted in this case?
A. You mean all the expert reports should be, what, keep the confidential? Is that what you're asking?
Q. I'm asking you, if when you reviewed the confidentiality and protective order, whether it was your understanding that that includes the expert reports that have been submitted in this case.
MR. MERRELL: Objection.

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Form.
THE WITNESS: I don't know. That's a legal issue. I don't know.
BY MR. NIGH:
Q. Do you believe it would be appropriate to take another person's expert report in this case and to try to submit them to various editorial boards?
MR. MERRELL: Objection to form.
THE WITNESS: I don't know, sir.
BY MR. NIGH:
Q. You don't have any understanding as to whether or not that would be unethical?
A. Well, it's nonethical or unethical, if it's in the public domain, I think everybody is entitled to make a comment on this publicly available document.
Q. So your answer would be you don't believe that it would be unethical

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to take a person's expert report and start showing it to editorial boards?
MR. MERRELL: Objection to form.
THE WITNESS: As long it's in the public domain, with the purpose of doing, for example, editorial or letter to the editors, I think it's appropriate. As long as you want educate the next generation how to do things right.
BY MR. NIGH:
Q. Okay. Let's take a look at Page 3 on the reliance list.
Looking under miscellaneous. It says, "All materials cited or referenced in my expert report and attachments."
Do you see that?
A. Yes, sir.
Q. And then it says, "This list includes item" -- "items plaintiffs' experts relied upon. By doing so" --

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"and this expert are not waiving any arguments or objections related to admissibility."
Do you see that?
A. Yes.
Q. Now, that plaintiffs is plural, correct?
A. What word? I'm sorry.
Q. Do you see the word "plaintiffs' experts"? That's plural, correct?
A. Yes.
Q. So is it your statement here that you considered all of the materials that all of the plaintiffs' experts considered?
A. No. As I said it before, I didn't read carefully about other expert witness reports. I glanced over your epidemiology plaintiff report. Other than that, I concentrate on Dr. Madigan's report.
Q. Now, this expert report has your signature. And attached to it is

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this reliance list.
Is it your testimony that you considered all of the materials or reviewed, considered or reviewed, all of the materials and all of the other plaintiffs' experts' reports?
A. Yes. I didn't use every single word from this plaintiff report. Right. That's what you're saying. I just utilized all the information that I got, and I think it's relevant I put more attention to it. For example, Dr. Madigan's publications listing, majority, almost everything is coming from your epidemiology expert witness, right.
Q. Did you --
A. So I said, oh, I don't have to worry about epi person anymore, because basically Dr. Madigan's report really reflecting what your epi person is going to say. So I just glanced over the expert witness report in epidemiology.
But other than that, I don't

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think other expert report are relevant to me for statistical analysis purpose. Besides, I really want to have an independent opinion myself. Don't actually influence it by other things.

Even I read the other reports, honestly, sir, I'm not expert at all, for a few. And quite a few things, I don't even understand what they are talking about.

Q. Okay. Did you -- go ahead.

A. So I just -- this is not efficiently use of my time. Right.

This -- my assignment mainly addressed issue and concerns about Dr. Madigan's report.

Q. Did you review any of Dr. Panigrahy's expert report?

A. No. No, sir.

Q. Did you review his list of references in any way?

A. No, sir.

Q. Did you review any of Dr. Hecht's report?

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A. No, sir.

Q. Did you review any of his list of references in any way?

A. No, sir.

Q. Did you review any of Dr. Lagana's report?

A. Who is the expert? May I ask?

Q. Dr. Stephen Lagana. Do you know who that is? Have you ever heard the name?

A. No. Nope.

Q. Have you ever heard -- you've never heard that name?

A. Well, it's one of your expert witness. I'm just asking you which expertise he's in -- or she's in.

Q. I see. Did you ever -- well, do you know which expertise he is?

A. I don't know. I'm asking you.

Q. Do you know which expertise Dr. Stephen Hecht is?

A. No, sir.

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Q. Do you know which expertise Dr. Panigrahy is?

A. No, sir.

Q. Did you ever review any of -- or did you review Dr. Lagana's reference list in any way?

A. No, sir.

Q. Do you recall if you even reviewed Dr. Etminan's reference list in any way?

A. That's epidemiologist, right?

Q. Right.

A. I didn't review carefully about the listing of publications he cited. But I only reviewed relevant statistical part from Dr. Madigan's.

Q. Let me turn the page to Page 1.

MR. NIGH: If we can blow up from the list of materials considered, Dr. Wei, all the way down to literature and include -- I mean -- yeah, and include --

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let's go down a little bit further. Blow it up even further down.

No. No. Down toward -- I just want to blow it up underneath where it says Dr. Panigrahy for literature. All the way down to literature. Yep. Right there. Thank you. I know I was a little unclear with my direction.

BY MR. NIGH:

Q. As you look at this, that's your name, Dr. Wei, correct?

A. Sorry, sir?

Q. That's your name, Dr. Wei, Ph.D., correct?

A. Well, sir, if you don't know my name by now, we are in trouble, right?

Q. You can just answer the question, please. Is that your name, Dr. Wei, correct?

A. I feel a little strange why are you asking those kinds of questions.

Answer of course, yes.

Q. And you're not a medical doctor, correct?
A. No, sir.
Q. Okay. It says list of materials considered.
Do you see that?
A. Yes, sir.
Q. Now, this list of materials considered was attached to the expert report that you signed. You understand that, correct?
A. Yes, sir.
MR. NIGH: And let's highlight Dr. -- 2021 expert reports with exhibits, highlight Dr. Stephen Hecht. Can we highlight that, please.
BY MR. NIGH:
Q. And then you did not, as -- your list of materials considered is incorrect because you did not review the report of Dr. Stephen Hecht or its exhibits, correct?
MR. MERRELL: Objection to

form.
THE WITNESS: That is not the word I understand it, sir.
When you say materials considered, that means that potentially those are the documents that I would have considered.
Whether I go in to read or not, that's my business. My interpretation of those two words, "materials considered," doesn't mean that I should utilize all the reports, and in my report, okay, and make a judgment and make assessment of what other expert witness reports.
That's my understanding. If I misunderstand this word, I apologize.
When I actually signed off this document, my understanding is that, well, this is a potential document, Dr. Wei, you should --

it may be helpful for you put in your report. I say fine.
Right. Lawyers say, okay, here are the reports. Whether you want to use it or not, because they already send to me, right.
I said, well, okay, this is part of a material that I considered. But that doesn't really matter I'm actually go through the report or not, right.
BY MR. NIGH:
Q. So even though you never even laid eyes on Dr. Stephen Hecht's report, never even looked at it, your testimony is that that's materials that you considered?
A. Yeah. You see, the reason that I don't even bother, because when I read Dr. Madigan's report, he didn't cite anything from those four doctors.
Right. The only thing is talking about epidemiologist. Right. So I said, well, okay, if he actually has

nothing to do with these four other expert witness reports, I'm not going to spend my time on those reports. Right. Rather I should put more energy reading Dr. Madigan's report. That's my understanding, sir.
The lawyers send me the information. Doesn't mean that I have to use it, right, I have to read it word by word.
I'm saying, yes, this is potentially material considered. But that's my interpretation, sir. If I misinterpret, I apologize.
Q. I want to make sure I understand. When you put the -- on this document, materials considered, that even if you've never even laid eyes or even looked at the document -- for example, Dr. Stephen Hecht's report -- you believe that that would be materials that you considered for your expert opinion?
A. That's my --
MR. MERRELL: Objection to

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form. Sorry.
THE WITNESS: That's my interpretation, sir.
BY MR. NIGH:
Q. So even though you never laid eyes --
MR. NIGH: Let's highlight Dr. Stephen Lagana, his expert report.
BY MR. NIGH:
Q. Even though you never even laid eyes on Dr. Stephen Lagana's expert report, it's your testimony that that would be materials that you considered for your expert opinion?
A. That's my interpretation, sir.
Q. So even though --
MR. NIGH: Let's highlight Dr. Dipak Panigrahy.
BY MR. NIGH:
Q. Even though you never even laid eyes on Dr. Dipak Panigrahy's expert report or its exhibits, it's your

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testimony that that would be material that you considered for your expert opinions?
A. That's my interpretation of the materials considered.
Q. Under literature where it says, "All materials cited in the report of Dr. Etminan" --
MR. NIGH: Let's highlight that.
BY MR. NIGH:
Q. You don't recall even ever laying eyes on the references that he cited, correct?
A. You mean the highlighted ones, you just highlight?
Q. Let me -- let me revise my question. You don't even recall ever even laying eyes on Dr. Etminan's reference list, correct?
A. I remember I glanced over. I not -- I don't recall, sir, how much detail I read through the citations or references in this expert witness report.

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Q. Let's take a look --
MR. NIGH: Let's highlight Dr. Stephen Hecht.
BY MR. NIGH:
Q. So even though you don't know what materials are cited in Dr. Stephen Hecht's report, it's your understanding that you considered those materials in forming your expert opinion; is that correct?
A. Yes, sir. If you allow -- if you allow me to say one thing. When the lawyers send me those documents, I feel obligated to let you know that I have this report.
But my understanding, whether I'm going to use it, whether I'm going to read it, that's different matter. That depends on myself.
So the material considered, including all the documents the lawyers send to me, plus something else, based on my expertise. That's my understanding for this listing for you, sir.

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If I misunderstand the words or your legal interpretation, I apologize.
As I said many times, every day I learn something new. If you can tell me that's not the right way to do it, I will revise what I -- my practice next time.
MR. NIGH: Let's highlight the next one below that.
BY MR. NIGH:
Q. So even though you don't know what materials were cited in Dr. Stephen Lagana's report, it's your understanding that you considered those materials in forming your expert opinion?
MR. MERRELL: Objection to form.
THE WITNESS: I don't think that it is actually necessary I need to read those report or listing of materials cited in this report to form my opinion on Dr. Madigan's report.

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MR. NIGH: And let's highlight the all materials in the -- for Dr. Panigrahy.
BY MR. NIGH:
Q. And even though you don't even know what materials are cited in Dr. Panigrahy's report, it's your testimony that those are -- that the materials cited in his report are materials that you considered?
A. Yeah, that's what the document -- the defendant lawyers send to me.
Q. Okay. Is it your belief that if the lawyers sent the document to you, even though you never laid eyes on it, that that would be materials that you considered?
A. Yes, sir.
Q. Okay. You also didn't review all of the materials cited in Dr. Madigan's report, correct?
MR. MERRELL: Objection to form.

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THE WITNESS: Now wait a second. What are you talking about now?
BY MR. NIGH:
Q. Dr. Madigan's report, did you review all the dietary studies that he cited in his report?
A. I did as much as I can. The paper -- lawyers send it to me. I read it carefully.
Q. Did you review all the materials cited in Dr. Madigan's report?
A. Well, I can go through his materials cited one by one to tell you which one I read it, which one I didn't.
Q. Do you believe that there are materials that you didn't read that are cited in his report?
MR. MERRELL: Objection to form.
Sorry.
THE WITNESS: I -- my recollection, I try my best to read every document or paper cited

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by Dr. Madigan. But I have to confess, like you said, it's two months old. My memory is not great compared with when I was young.
So I'm not quite sure that I read every paper, single paper, or document cited by Dr. Madigan.
But if I don't list the papers on this Exhibit B, that means I didn't read it. Right.
BY MR. NIGH:
Q. But even if you listed papers on this Exhibit B, we've established that that doesn't mean that you read it either, right? Or even laid eyes on it?
A. That's correct.
Q. Okay. So if you can help me out here.
Under MDL pleadings and general documents, are there any of those that you never even read?
A. You mean on this highlight

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portion?
Q. Well, yeah, you can see what I've blown up here. You can see underneath there. MDL pleadings and general documents, are there any of those that you've never read?
A. Oh, I said for example, Hecht, Lagana, Panigrahy.
Q. Wait. I need to be clear. I'm looking under -- do you see where it says MDL pleadings and general documents? Under there, there are six different documents there. Are there any of those that you didn't read?
A. I don't remember I read the letter from Lori Cohen to the judge.
Q. Okay.
A. I don't remember.
MR. NIGH: Let's highlight that one.
BY MR. NIGH:
Q. Are there any other materials there? Do you believe that you ever laid eyes on the letter from Adam

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Slater providing an overview?
A. Well, sir, if you can show me the cover of this document, I probably can remember. But right now --
MR. NIGH: No, let's not highlight that one, the letter.
BY MR. NIGH:
Q. I'm sorry. I didn't mean to interrupt you.
A. So even for the letter from Lori Cohen to judge, honestly, sir, if you can show me, that would probably bring my letter back, right, to see if I read the letter or not, right.
Q. Okay. So on these six here, just do you recall reviewing any of these six documents? Which ones do you recall reviewing and which ones do you not recall reviewing?
A. Yeah, I believe the first one, second one. I think the fourth one I remember I read it. But I'm not quite sure the economic monitoring complaint, that one I read. I don't remember now.

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Q. And the two letters, you don't remember reading those either?
A. Correct. I don't remember exactly I read or not.
Q. How about under discovery documents cited by plaintiffs' experts.
MR. NIGH: Let's highlight that.
BY MR. NIGH:
Q. Do you recall reviewing either of those two documents?
A. No. I didn't read the spreadsheet of NDMA. Actually don't.
Q. You don't recall ever laying eyes on the spreadsheet of "NDMA Test Results For ZHP API" or the Torrent Pharmaceuticals Limited document, correct?
A. Yeah, I know they sent it to me, but I notice that Dr. Madigan didn't even mention anything, so I didn't read it.
Q. Okay. And I'm sorry. Is it your testimony that Dr. Madigan never

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mentioned anything about test results?
A. Well, he didn't mention this spreadsheet citing this document. So I didn't read it.
Q. It's your testimony both the spreadsheets of "NDMA Test Results For ZHP API" and the "Torrent Pharmaceutical Limited Valsartan Impact Assessment of NDMA," that Dr. Madigan didn't review those so you didn't review them either; is that correct?
MR. MERRELL: Objection to form.
THE WITNESS: That's my recollection. I don't see anywhere in his report talking about T-O-R-R-E-N-T, the company's name.
MR. NIGH: Okay. All right. Let's go ahead and highlight those two.
BY MR. NIGH:
Q. Okay. Under literature, do you recall reviewing the EPA NDMA

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technical fact sheet?
A. No, sir.
MR. NIGH: Let's highlight that one.
Let's go ahead and blow up the rest of the literature. Okay.
BY MR. NIGH:
Q. Do you recall reviewing De Stefani, E.; Galer, cited 1992? Do you recall reviewing that document?
A. That's interesting. I vaguely remember this name. But I don't remember I review it or not, sir.
Q. Okay. The next one. "EPA, High Fat Foods and the Risk of Lung Cancer." Do you remember reviewing that document?
A. I would say most likely I did not.
Q. Okay. "FDA, Consumption of Nitrate, Nitrite and Nitrosodimethylamine and the Risk of Upper Aerodigestive Tract Cancer."
Do you recall reviewing that

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document?
A. That one, I think. I think, but I'm not quite sure, sir.
Q. Okay.
A. Yeah, again, memory is fuzzy.
Q. "FDA, Dietary Nitrosodimethylamine and the Risk of Lung Cancer: A Case-Control Study From Uruguay."
Do you recall reviewing that document?
A. I don't think so. This one I probably didn't read it.
Q. Okay.
MR. NIGH: Next page.
BY MR. NIGH:
Q. Friedman, Furberg and DeMets, "Fundamentals of Clinical Trials."
Do you recall reviewing that? It looks like a textbook.
A. This is not reviewing. This is actually I provide the references,

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sir.
Q. Okay. So you did review that material, correct?
A. Yeah. This -- this a book, like you said.
Q. Okay. Galer, DM, et al., "Risk of Colorectal and Other Gastrointestinal Cancers After Exposure to Nitrate, Nitrite, and N-Nitroso Compounds."
Do you recall reviewing that document?
A. I think I remember this one, yes.
Q. There are two Gomm studies. Do you recall if you -- there are two Gomm reported here. Do you recall if you reviewed them both?
A. I think of Gomm as -- English version, I read the English version.
Q. You don't recall reviewing the PubMed abstract?
A. I'm not quite sure I read

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that part because I read the paper. The abstract, I didn't remember. So that part, I don't remember.
Q. Okay. Goodman, MT, et al., "N-Nitroso Dimethylamine Hazard Summary."
Do you recall reviewing that document?
A. Yes.
Q. Okay. Hidajat, "Lifetime Exposure to Rubber, Dust, Fumes, and N-Nitrosamines and Cancer Mortality."
Do you recall reviewing that document?
A. Yes.
Q. IARC, 1978, "Some N-Nitroso Compounds."
Do you recall reviewing that document?
A. I not remember this one.
Q. Okay. IARC --
A. I don't --
Q. Sorry, go ahead.
A. I don't remember this -- next one I remember. But not this one.

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MR. NIGH: Let's scroll down to where we can see IARC, the second one.
BY MR. NIGH:
Q. Do you recall reviewing IARC, "Structure of Dietary Measurement Error: Results of the OPEN Biomarker Study"?
A. Yeah, I think I read this one.
Q. Okay. Jakszyn, "Red Meat, Dietary Nitrosamines, and Heme Iron and Risk of Bladder Cancer."
Do you recall reviewing that document?
A. The name is familiar, but I believe maybe, again, if you show me the cover -- abstract, I probably can remember. I apologize. My memory is fuzzy here.
Q. Johnson, GE, "Nitrosamines And Heme Iron and the Risk of Prostate Cancer in the European Prospective Investigation..."

Do you recall reviewing that document?
A. Yes, sir.
Q. Knekt, "Risk of Colorectal and Other Gastrointestinal Cancers."
Do you recall reviewing that document?
A. Yes, sir.
Q. Larsson, "Processed Meat Consumption, Dietary Nitrosamines, and Stomach Cancer."
Do you recall reviewing that document?
A. Yes, sir.
Q. Loh, "N-Nitroso Compounds and Cancer Incidence: The European Prospective Investigation Into Cancer and Nutrition."
Do you recall reviewing that document?
A. Yes, sir.
MR. NIGH: Let's continue further down.
BY MR. NIGH:

Q. Madigan, D., et al., "A Systematic Statistical Approach to Evaluating Evidence From Observational Studies."
Do you recall reviewing that document?
A. Yes, sir.
Q. Is it your understanding that Dr. Madigan has published extensively on the limitations of observational studies?
A. I'm sorry, sir. Dr. Madigan saying what limitation of the observational study, you said?
Q. Is it your understanding that Dr. Madigan has published extensively on the limitations of observational studies?
A. Yes.
Q. McCaw, et al., "How to Quantify and Interpret Treatment Effects in Comparative."
Do you recall reviewing that document?

A. I wrote that paper, sir.
Q. Okay. Next one. "Clinical Studies of COVID-19." You discussed this in your testimony, so do you recall reviewing that document?
A. That's my paper.
Q. Okay. McCaw, Zack, Kim, Dae, and Dr. Wei, that's obviously your paper, correct?
A. Yes, sir.
Q. Pak, et al., "Interpretability of Cancer Clinical Trial Results Using Restricted Mean Survival Time."
Do you recall reviewing that document?
A. It was my paper.
Q. Okay. Pottegard. You reviewed that document, correct?
A. Yes, sir.
Q. Rogers, MAM, "Laboratory Analysis of Valsartan Products."
Do you recall reviewing that document?

A. Yes, sir.
Q. Snodin DJ, et al., "Short Commentary on NDMA Contamination of Valsartan Products."
Do you recall reviewing that document?
A. I vaguely remember this name. But honestly I don't remember.
Q. Okay. Song, et al., "Dietary Nitrates, Nitrites, and Nitrosamines Intake and the Risk of Gastric Cancer: A Meta-Analysis."
Do you recall reviewing that document?
A. Yes, sir.
Q. Uno, et al., "Moving Beyond the Hazard Ratio in Quantifying the Between Group Difference."
Do you recall reviewing that paper?
A. It's my paper.
Q. Wasserstein, that's the ASA statement that we just looked at.
So you reviewed that

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document, correct?
A. Yes.
Q. Zhao, Tian, and Claggett, "Estimating Treatment Effect With Clinical Interpretation From a Comparative Clinical Trial."
Do you recall reviewing that document?
A. It was my paper.
Q. Okay. Zheng, et al., "Permitted Daily Exposure Limits For Noteworthy N-Nitrosamines."
Do you recall reviewing that document?
A. Yes, sir.
Q. Zheng, Stuff, Tang, "Dietary N-Nitroso Compounds and Risk of Pancreatic Cancer."
Do you recall whether or not you reviewed that document?
A. Yes.
Q. The Zheng, the would be right before that -- the Zheng, "Permitted Daily Exposure Limits For

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Noteworthy N-Nitrosamines. Environmental and Molecular Mutagenesis."
Do you know which cancer type they are reporting there? Do you recall?
A. I don't remember. I don't remember. I know the second paper very well, the second Zheng.
Q. Zhu, Z-H-U, "Dietary N-Nitroso Compounds and Risk of Colorectal Cancer."
Do you recall whether or not you reviewed that document?
A. I believe so.
Q. Okay. Now, under miscellaneous, it states, "This list includes items plaintiffs' experts relied upon." But we obviously know now that you haven't reviewed or even laid eyes on many of these expert reports, correct?
A. Yeah, there is a list that I need to cite in my report.
Q. Okay. Looking at your table.

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MR. NIGH: Sorry. Back to the -- sorry, back to the materials considered.
BY MR. NIGH:
Q. Under these materials considered, you don't have the Pobel study at all in that literature.
Is it your belief that you didn't review the Pobel study?
A. You mean the Danish study?
Q. No. That's Pottegard.
A. I'm sorry. Which one are you talking about? I'm sorry.
Q. Pobel study, P-O-B-E-L.
MR. NIGH: Let's go ahead to -- let's blow it up, the reliance list.
And let's go to the next page, because you had them in literature. You had them in alphabetical order by their author.
BY MR. NIGH:
Q. So you can see here that's

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the Ms., and that's going to be the next page where we have P.
You don't have Pobel, P-O-B-E-L, on here.
A. Yeah.
Q. So do you recall whether or not you ever reviewed those materials?
A. Well, I'm not too sure now. I mean, I don't remember that particular publication, sir.
Q. Okay. Let's go back to the prior page.
MR. NIGH: Let's blow that up.
BY MR. NIGH:
Q. La Vecchia.
MR. NIGH: It's hard to see. We can blow up -- yeah, there we go.
BY MR. NIGH:
Q. La Vecchia. You don't have that on your list of reliance materials.
Do you recall whether or not you ever reviewed the La Vecchia

materials?
A. I don't remember, sir.
Q. Okay. Keszei, K-E-S-Z-E-I, it's not listed here on your reliance materials.
Do you recall whether or not you ever reviewed those materials?
A. I don't recall, sir.
Q. Let's go back to the prior page. You have one De Stefani study listed here.
Do you recall reviewing any other De Stefani materials?
A. I don't recall, sir.
MR. NIGH: We can go ahead and take that down.
Let's go ahead and take a break at this time and I'm going to try to get through and trim down to the last things that I have.
THE VIDEOGRAPHER: The time right now is 11:07 a.m. We're off the record.

(Short break.)
THE VIDEOGRAPHER: The time right now is 11:25 a.m. We're back on the record.
MR. NIGH: Okay. Let's go ahead and pull up LP-1600. This was marked Exhibit 2 previously.
BY MR. NIGH:
Q. Doctor, you'll recall that in the deposition notice that we started with, we asked for production of documents from you.
Do you recall that?
A. Yes, sir.
Q. And are you aware that in response to our production of documents, that we were produced over 500 documents?
A. No, I don't know.
Q. Do you believe as you reviewed the request for documents, would you have ever thought that there would be over 500 documents that were responsive to our request?
MR. MERRELL: Objection to form.
THE WITNESS: I don't know, sir.

BY MR. NIGH:
Q. Well, let's take a look at it.
MR. NIGH: Number 1. Let's go to the second page. This is defendants' -- actually, let's go to the first page and blow up defendants' responses and objections.
BY MR. NIGH:
Q. Do you see that? So this is the response to our request for documents.
Do you see that?
A. Yes, sir.
Q. And let's take a look at the second page.
MR. NIGH: Let's blow up this one.
BY MR. NIGH:
Q. "Copies of all invoices for work performed in connection with any consultation or expert work performed."
That would only be the one document, the one invoice that you sent to us, correct?
A. Yes, sir.
Q. Let's take a look at the next page. Number 2, "Copies of any notes, written or electronic, reflecting consulting or litigation work that has not been documented in invoices."
You didn't have any of those documents, correct?
A. It's on my draft of the report.
Q. Okay. Just draft reports. But other than that -- which we're not entitled to receive your draft reports. Other than that, it's your testimony that you didn't have any other documents that are responsive to this, correct?
A. Yeah. Correct, sir.
Q. Next, Number 3, "Copies of any notes or other documentation,

including PowerPoints for any presentations, seminars or classes given by Dr. Wei with regard to the risk and benefits of any angiotensin II receptor blockers or nitrosamines."

It was your testimony that you didn't have any documents that were responsive to this request, correct?

A. Correct.

Q. Number 4, "Copies of any documents or articles relied upon for the opinions set forth in the expert" -- "in the report served if not listed in the report."

Do you have an approximation as to how many documents or articles that you relied upon for the opinions set forth in your report?

A. The documents I cited in my report, that's all the -- all I have.

Q. Okay. It's certainly less than 50 documents or articles that you relied upon for the opinions set forth in your report, correct?

MR. MERRELL: Objection to form.

THE WITNESS: I don't know the number. I didn't count it, sir. I'm sorry.

BY MR. NIGH:

Q. You can't say right now as you speak that you reviewed less than 50 documents or articles in relying upon the opinions set forth in your report?

MR. MERRELL: Objection to form.

THE WITNESS: Well, if we can go back to my report, I will tell you exactly the papers documents that I cited.

BY MR. NIGH:

Q. I don't need an exact number here. Do you know whether or not it's approximately 50, less than 50, or are you able to say whether or not it's less than 100?

MR. MERRELL: Objection to form.

THE WITNESS: Well, I prefer not to use a guess number. Sorry, sir. I just want to have an exact number for you.

BY MR. NIGH:

Q. Okay. Number 5, "Copies of any documents or articles reviewed in connection with the report served, whether or not listed in the report or attachments thereto."

Do you see that request?

A. Yes, sir.

Q. Number 6. "Any illustrations, PowerPoints, images, charts, tables, or demonstrative exhibits that may be used by or with Dr. Wei in connection with the Daubert hearing or trial testimony."

Do you recall that you told me that you didn't have any of these -- any extra documents reflecting this, other than your report, correct?

A. Yes. I think I remember. My answer is at this point, I didn't have

it. But we probably going to have some extra PowerPoint maybe, maybe for the court hearing or something else, in the future.

Q. Number 7, "Documentation of any research grant the witness has provided to study any ARB, nitrosamine, or health effects potentially related thereto."

And do you recall telling me that you didn't have any documents reflective of this, correct?

A. Right.

Q. Number 8, "Documentation of any research the witness has performed with regard to any ARB, nitrosamines, or health effects potentially related thereto."

And you recall previously telling me that you didn't have any of these documents, correct?

A. Yes, sir.

Q. Number 9, "Copies of any documents, including protocols or

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information about medication side effects."
Do you recall telling me that you didn't have any documents responsive to this request, correct?
A. Correct.
Q. Number 10, "Any documents or other communications the witness has received from any person or entity with regard to nitrosamine impurities."
Do you recall telling me that you didn't have any of these documents, correct, any documents responsive to this response, or -- strike that.
Number 10, "Any documents or other communications the witness has received from any person or entity with regard to nitrosamine impurities in any ARB or other drug."
Do you recall telling me that you do not have any documents responsive to this request, correct?
A. No, sir.

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Q. It is correct that you don't have any documents responsive to this request, correct?
A. Well, sir, one thing that I don't really completely understand, it says "or other drugs." That means impurity in other drugs? Is that what you're talking about?
Q. Is it your testimony that you produced us documents that were responsive to this request?
A. No. My question is, I did read one paper about the contamination or impurity for other drug, not this one.
Q. I see.
A. Actually, I shared it with you. Honestly, Zantac, you know, the Zantac case. I read one paper because the lawyer send it to me, okay. That was before even we talking about this case. That probably was like five or six months ago.
Q. I see. So you didn't have any documents that you produced to us

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that were responsive to Number 10, correct?
A. Not for this case, sir.
Q. Number 11, "Any communication from the witness to any person or entity with regard to nitrosamine impurities."
Do you recall that we talked about this request and you advised that you didn't have any documents responsive to this request, correct?
A. Correct.
Q. Number 12, "Any textbook referenced by the witness in forming his opinions."
Do you recall telling us that there was one textbook that you referenced, correct?
A. Correct.
Q. Now, Number 12 which asked for the textbooks, there was one document. Number 1, which asked for the invoices, there was one document, correct?

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A. Yes, sir.
Q. And other than Number 1 and 12, the only other request that you had documents responsive to were Number 4 and 5.
MR. NIGH: Let's turn to Page 4 and show those two document requests. And Number 4 as well, if we can put that up at the same time.
BY MR. NIGH:
Q. Do you see there, "Copies of any documents or articles relied upon for the opinions set forth in the report served, if not listed in the report."
And, "Copies of any documents or articles reviewed in connection with the report served, whether or not listed in the report or attachments thereto."
Do you see that?
A. Yes, sir.
Q. Now, in terms of that, do you believe that you had over 500 documents that would be responsive to

that request, those two requests?
MR. MERRELL: Objection to form.
THE WITNESS: On your side -- or -- I don't know the number, sir.
BY MR. NIGH:
Q. Do you believe that there would be a total of over 500 documents that would be responsive to these two requests, that there were either copies of any documents or articles relied upon for the opinions set forth in your report, or copies of any documents or articles that you reviewed in connection with the report that you served?
Do you believe that there are over 500 articles that would be responsive to these two requests?
MR. MERRELL: Objection to form.
THE WITNESS: Sir, I have no opinion on this.
BY MR. NIGH:

Q. Well, I'm asking you your answer -- this request for documents is directed to you. So I'm asking for your opinion.
Do you believe that you reviewed over 500 articles that you either relied upon for opinion in your report, or that you reviewed in connection with the report that you served?
MR. MERRELL: Object to form.
THE WITNESS: Sir, I don't even understand your question.
You know, basically, I answer your question. Number 4, Number 5. I said I don't have anything provided to you.
You know, that's my -- my side.
I don't care other people, your expert witness, how many articles they didn't cite. That's not my business. You should talk

to the lawyers instead of talk to me.
BY MR. NIGH:
Q. My question is not what our experts looked at. My question is what you looked at. Do you understand?
A. I honestly answered your question. I honestly delivered anything I had. I'm just saying that I don't have anything to provide to you, sir.
Q. Do you believe that you looked at over 500 documents that you either relied upon for the opinions in your report or that you reviewed in connection with the report that you served? That's my question.
MR. MERRELL: Objection to form.
THE WITNESS: Sorry, sir. I don't review more than 500, sir. I mean, what is the number coming -- I don't even understand. What is 500, this discrete number, referring to? You're just making

number for me or something?
BY MR. NIGH:
Q. No, I'm just asking you.
My question to you is, do you believe that you reviewed over 500 documents that you either relied upon for the opinions in your report, or reviewed in connection with the report that you served? I think you're telling me no, you didn't review anywhere close to 500 documents; is that correct?
A. Yeah, I don't.
Q. Okay. Do you understand that when we served this request for documents, that we received in response over 500 documents in response to our request for documents from you? Were you aware of that?
A. No, sir.
Q. Do you have any approximation as to the number of documents that you relied upon for the opinions set forth in your report, or that you reviewed in connection with the

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report that you served?
A. I cannot give you exact numbers, sir. I have to go through my report, all the papers I reviewed, and I can tell you exactly the number.
MR. NIGH: Okay. Let me just see if I have any more questions. I'll be just two minutes.
THE VIDEOGRAPHER: Are we going off the record?
MR. NIGH: Yeah, we just need a couple minutes here. Just wanted to see if I --
THE VIDEOGRAPHER: The time right now is 11:40 a.m. We're off the record.
(Short break.)
THE VIDEOGRAPHER: The time now is 11:43 a.m. We're back on the record.
MR. NIGH: Dr. Wei, I have no more questions at this time. I would reserve the balance of my

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time for any potential redirect. But thank you for your time. Appreciate it.
THE WITNESS: Thank you, sir.
MR. MERRELL: Mr. Nigh, we have -- I do have questions. Mr. -- or sorry, Dr. Wei has a conference call that he needs to do. So can we reconvene at 1:30? And we won't be very long but he does have a conference call he needed to cover today.
MR. NIGH: Yeah, let me see. How long do you think your questions are?
MR. MERRELL: I think probably 20 -- 20, 30 minutes, something like that.
(Whereupon a discussion was held off the stenographic record.)
MR. NIGH: That's fine for me. We can reconvene at that time.

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MR. MERRELL: Okay. Thank you.
THE WITNESS: Thank you, sir.
MR. NIGH: Thank you.
THE VIDEOGRAPHER: The time right now is 11:45 a.m. We're off the record.
(Lunch break.)
THE VIDEOGRAPHER: The time right now is 1:36 p.m. We're back on the record.
- - -
EXAMINATION
- - -
BY MR. MERRELL:
Q. Dr. Wei, I just wanted to ask a few follow-up questions from the last two days.
First, I want to ask some questions about your background. Are you a professor of biostatistics department?
A. Yes, sir.
Q. In that capacity, did you

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give academic lectures?
A. Yes, sir.
Q. Do you also supervise graduate students?
A. Yes, sir.
Q. Did you publish scientific literature?
A. Yes, sir.
Q. Have you been an editor of journals?
A. Yes, sir.
Q. Have you made decisions about what articles should or should not be accepted for publication?
A. Yes.
Q. Have you made editorial decisions about publications?
A. Yes.
Q. Okay. I want to take a look at your -- just a couple things in your report, which you have in front of you. I'm just going to refer to it here.
And take a look at Page 5, which talks about your assignment.

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A. Yes.
Q. Were you asked to evaluate Dr. Madigan's opinions specifically?
A. Yes.
Q. Were you asked to evaluate Dr. Madigan's analysis of the dietary and occupational studies on NDMA and NDEA and the risk of cancer?
A. Yes.
Q. And were you asked to assess Dr. Madigan's extrapolation of the dietary and occupational studies on NDMA and NDEA to valsartan with NDMA impurities?
A. Yes, sir.
Q. Did you look at the same articles Dr. Madigan looked at for his report?
A. Yes, sir.
Q. Did you review some additional studies?
A. Yes, I did.
Q. Which ones, for example, did you look at?

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A. Most noteworthy -- the two that's really interesting is the Danish study and the German study of impurity of valsartan.
Q. Those are also called the Gomm and Pottegard studies?
A. Yes.
Q. Did you conduct your own search for literature on valsartan with NDMA impurities in the literature?
A. I did.
Q. And were you able to interpret all of these studies that you looked at as a biostatistician?
A. Yes.
Q. Okay. Let's take a look at your conclusions in your expert report?
(Whereupon, a discussion was held off the stenographic record.)
BY MR. MERRELL:
Q. If you turn to Page 22.
A. Yes.
Q. I'm sorry, Page 23. What conclusion did you reach about

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extrapolating the results of the dietary and occupational studies to the risk of cancer from valsartan with NDMA and NDEA impurity?
A. Based what I read -- learned from Dr. Madigan's report I cannot agree with Dr. Madigan. In my opinion, there is no evidence at this stage we can claim the impurity in valsartan was associated with the cancer incidence increase.
Q. And did Dr. Madigan properly rely on these dietary and occupational studies to reach that conclusion?
A. Don't think --
MR. NIGH: Objection. Form objection.
BY MR. MERRELL:
Q. Is that listed out in your report?
A. Yes, sir.
Q. We'll move to another topic. Do you recall being shown similarities between your expert report here and your expert report in other cases from the

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past?
A. Yes, sir.
Q. Were those similarities that were shown to you, were those regarding your qualifications and general background statistical principles?
MR. NIGH: Form objection.
THE WITNESS: Statistic principles actually valid, guess, what, 20 or 30 years ago.
BY MR. MERRELL:
Q. So those statistical principles that carried over from your prior expert reports to the valsartan report, had those changed since you wrote them?
MR. NIGH: Form objection.
THE WITNESS: No.
BY MR. MERRELL:
Q. And have you been deposed for over two days and for over eight hours at this point?
MR. NIGH: Form objection.
BY MR. MERRELL:

Q. If your report was truly identical --

(Whereupon a discussion was held off the stenographic record.)

THE WITNESS: The answer is yes.

(Whereupon a discussion was held off the stenographic record.)

BY MR. MERRELL:

Q. If your report was truly identical to these reports that counsel showed you, wouldn't you anticipate your deposition would take considerably less time than that?

MR. NIGH: Form objection.

THE WITNESS: I would hope so.

BY MR. MERRELL:

Q. All right. These expert reports that you were shown from other cases, did some of those reports involve evaluations of different drugs?

A. Yes, sir.

Q. In preparing your expert

report in the valsartan litigation, is your report specific to valsartan in your opinions regarding the study and material involved and that you've reviewed in this litigation?

A. Let me -- Counsel, let me just take a few seconds to explain to you, maybe better answer to your question.

For example, the plaintiff lawyer provide my expert witness, Taxotere and Celebrex, and also the valsartan, of course, the current case.

If you notice, Celebrex and also the Taxotere cases, they all pretty much involving clinical trial data. And we actually used this clinical trial methodology to assess the plaintiff expert witness reports.

On the other hand, in the current case, valsartan impurity, there were no clinical trials data available. So we had to use a different methodology to assess and evaluate Dr. Madigan's

report.

Q. Your methodology here differed a bit from other cases because of the data available?

A. It's actually the nature of the cases. The principle of methodology, all the same. Example -- I use the same example demonstrate across many trials.

On the other hand, every case, specifically we have to use different methods to analyze -- to assess the validity of the claims.

Q. Is that what you've done here?

A. Yes, sir.

Q. Let me turn to another topic. Do you recall your testimony on -- from your deposition yesterday on multiple comparison adjustment?

A. Yes, sir.

Q. Do you recall being asked about your use of the Bonferroni correction?

A. Yes, sir.

Q. Is that a multiple comparison adjustment tool?

A. It's one of the tools, because Dr. Madigan used the P-value to assess the group difference. So the mostly commonly used method still Bonferroni. If Dr. Madigan used different way to quantify the difference between exposure and non-exposure groups, we would have used a different methodology to assess his claims.

But I'm sorry. One thing I want to emphasize, Dr. Madigan did not make any adjustment for his comparison.

Q. Okay. Let me ask you -- I'll turn to another topic. Do you recall being asked during the course of your deposition about various studies, including colorectal and lung cancer studies, and having the results represented to you without having the benefit of the publication in front of you?

MR. NIGH: Form objection.

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THE WITNESS: Correct.
BY MR. MERRELL:
Q. And to be able to fully answer the questions presented to you, would you need to have the article in front of you?
MR. NIGH: Form objection.
THE WITNESS: Yes.
BY MR. MERRELL:
Q. Did you ask for the article?
A. I did.
Q. And was it provided to you?
A. No.
Q. Are you able to know from memory all the information in the various studies that you've reviewed in this case?
A. It would be difficult.
Q. All right. Let me just show you -- take a look at Table 1 of Dr. Madigan's report. It should be in the pile next to you. It's on Page 7.
A. Yes. Yes, sir.
Q. Now, Table 1 has a list of

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several studies that Dr. Madigan reviewed, right?
A. Yes.
Q. And there's various columns in the table, right?
A. Yes.
Q. Are all the columns and abbreviations defined in this table?
A. Not every column.
Q. Was that Dr. Madigan's responsibility to define the abbreviations and columns?
MR. NIGH: Form objection.
THE WITNESS: I believe so.
BY MR. MERRELL:
Q. Have you reviewed the studies referenced in Table 1?
A. Yes.
Q. Did the lack of the abbreviations or definitions, did that impact your ability to review and analyze these studies referenced in the chart?
MR. NIGH: Form objection.
THE WITNESS: That's

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correct.
Sorry. That's correct. I don't even have to know the abbreviation -- for example, CC or C on the third column -- to actually evaluate each study.
BY MR. MERRELL:
Q. All right. And do you recall being asked information about those studies without the benefit of having them in front of you?
A. Correct.
Q. Are you able to recall from memory all the details of those studies from Table 1?
A. It's difficult.
Q. Let me turn to another topic. You were asked about your list of materials considered today.
Do you recall that?
A. Yes.
Q. And you can put aside Dr. Madigan's report.
Does the materials

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considered list include all the documents provided to you by defense counsel?
A. Yes.
Q. And sitting here today, can you recall every document from that list just by being shown the list whether you reviewed it in two months -- in the last two months in preparing your report?
MR. NIGH: Form objection.
THE WITNESS: It would be difficult without seeing the document on the paper.
BY MR. MERRELL:
Q. Did plaintiffs' counsel, did he actually show you any of the studies or documents during his questioning to help you remember had you reviewed it?
A. No.
Q. And did defense counsel provide you the articles cited in Dr. Madigan's report?
A. I'm sorry. Say it again.
Q. Did defense counsel provide you a set of articles that are cited in

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Dr. Madigan's report?
A. No.
Q. The articles -- during the course of your review of this case, did you -- were you provided, before you put your expert report together, the articles in Dr. Madigan's report?
A. Yes.
Q. And if I were to ask you the name of an article or document, just from your materials considered list, are you going to be able to necessarily tell me whether you reviewed it based solely on the name?
MR. NIGH: Form objection.
THE WITNESS: That would be difficult.
BY MR. MERRELL:
Q. Okay. And one final thing, and we can wrap up.
I'm going to hand you what was marked earlier, I think, Exhibit 2. It's the objections to the notice of videotaped deposition.

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A. Yes, sir.
Q. Do you recall towards the end of your testimony today, you were asked about over 500 documents being provided to plaintiffs' counsel in response to the notice of deposition?
A. Yes, sir.
Q. And then were you shown various requests from the notice and objections to the request?
A. Yes.
Q. Take a look at Page 5 of the objections -- I'm sorry, Page 4.
A. Yes.
Q. And do you see Request Number 4 is listed there?
A. Yes, sir.
Q. And if you look at the bottom, does it state, "Defendants will produce a copy of all electronically available documents identified on Dr. Wei's list of materials considered prior to deposition"?
A. Yes.

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Q. Okay. And if you look at -- on the next page, the same response for Number 5. It says the same thing?
A. Yes.
Q. So is it your understanding plaintiffs' counsel, in response to their notice for deposition, was provided all the documents from your materials considered list?
A. Yes.
Q. Okay. Is there anything else that you want to explain or add to your testimony at all today?
MR. NIGH: Form objection.
THE WITNESS: No.
MR. MERRELL: I don't have any further questions.
MR. NIGH: Okay. I do have some questions.
Okay. We're going to pull up LP-1609.
(Document marked for identification as Exhibit Wei-15.)

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MR. NIGH: We're going to mark this Exhibit Wei-15.
Let's go ahead and blow this up.
- - -
EXAMINATION
- - -
BY MR. NIGH:
Q. Now, Doctor, you never saw the list of materials that was provided to us from defense counsel, correct?
A. You mean this document?
Q. Yeah. You never actually saw yourself the list of materials that was presented to plaintiff's counsel in conjunction with the notice of deposition, correct?
A. Yeah. That's correct.
Q. Okay. I want you to be able to see. This is a screen shot that shows all the documents that were provided to plaintiff's counsel in response to Questions 4 and 5. Do you remember there was one document for, you know, a couple

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other questions. But this is what we received.
So that's the first page.
MR. NIGH: Let's take a look at the second page. The second page.
Let's take a look at the third page. Third page.
Let's look at the fourth. There's the fourth page.
Let's look at the fifth. There's the fifth page.
BY MR. NIGH:
Q. And I can represent to you that each of these PDFs is another document.
Do you understand that?
A. Yes.
Q. Okay. Let's take a look at the next page. There's another list.
Let's take a look at the next page. You can see all those documents.
Let's take a look at the

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next one. You can see those.
Let's take a look at the next page. Do you see those?
Take a look at the next page. You can see those there.
Let's take a look at the next page. You can see those.
Let's take a look at the next page. You can see those there.
Let's take a look at the next page.
MR. NIGH: Let's go ahead and blow up that a little bit more so it can be seen.
BY MR. NIGH:
Q. Okay. You can see those. Let's take a look at the next page.
A. I hardly can see it, sir. This is too small for me.
Q. Do you see the numbers, now I want you to --
MR. NIGH: Let's blow up a couple of these ones here, where we can see them even -- the top

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ones.
BY MR. NIGH:
Q. Do you see that? Now you can start seeing numbers on documents. So we can see it goes two, three, four, five, six, seven, eight, nine, ten.
Do you see that?
A. Yes, sir.
MR. NIGH: Let's keep scrolling through.
Scroll on down. Do you see all the way to 25. Scroll down. Let's keep scrolling down.
Do you see it's going in numerical order, not a number is missed.
Keep going down. All the way down to 60.
BY MR. NIGH:
Q. Did you see that, 60 in a row?
A. Yeah.
Q. Okay. Let's keep going down. Let's keep scrolling down so you

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can see all these documents provided to us.
Now we can see some more numbers. You see one, two, three, four, five, six, seven, eight, nine, ten, 11.
MR. NIGH: Let's keep scrolling down. More and more. This is going to take a while. So let's scroll down with some speed.
BY MR. NIGH:
Q. Let me know if you can't -- if you're not following with the speed we're going.
A. I cannot follow. You are going too fast.
Q. So we're going all the way -- 41, 42, 43, 44, 45. It's sequential. And we keep going down. There's not a number being missed here.
MR. NIGH: Let's keep going. Keep scrolling down.
52, 53, 54, 55. You can see there's not a number missed.
Let's keep going down.

Still 69. Let's keep going.
70. 71.
We're going all the way through here. We're all the way to 80 now. Not a number is missed.
Keep going down. 91. Not a number missed.
Now we see 92. We're scrolling all the way down. 102, not a number missed. All the way to 115.
BY MR. NIGH:
Q. Are you following so far?
A. I can barely follow the number, the numerical number.
Q. Do you see 116, all the way to 123?
A. Yeah.
Q. Do you see that? Okay.
MR. NIGH: Let's scroll down. Let's do 124 on down to what else we can see on the screen. 124 all the way to 132.

BY MR. NIGH:
Q. Do you see that?
A. I really can't see the numbers.
Q. Right. You see the numbers. You can see it's sequential, there's a document for each one of those, correct?
A. But actually, on the record, I guess it's so fast so that you guys -- what kind of a document are you referring to for each number?
Q. Well, all I need you to see is the number of documents. That's it at this point. That's the point here.
So as long as we can see that there's that number of documents.
MR. NIGH: Let's keep going. All the way to 136. Do you see that? We can keep going down.
137 all the way to 146.
147 on that page too.
Keep going.
148 all the way to 159.
And what I'll ask now is

just to scroll through to the end. These numbers are all in sequential order. So let's just scroll through.
See how many of them there are. Let's keep going. Let's keep going. Let's keep going.
We are all the way to 249 now.
Let's keep going. Let's keep going. Let's keep going. We can keep scrolling.
We're all the way to 364.
Keep going.
It's all the way at 381. We're in the 400s now.
Keep going.
You can see we're almost to 500 now.
Keep scrolling.
That's 500 documents in there just from -- that are numbered. We saw many others that were numbered differently.

Now we can put this down.
BY MR. NIGH:
Q. And I'll represent that this --
MR. NIGH: We can take this off.
BY MR. NIGH:
Q. I'll represent that this is a screen shot of all the documents that were provided to us, an index of each of them in response to the deposition notice.
And my question to you is: As we stated it previously, you didn't review anywhere near 500 documents, correct?
MR. MERRELL: Objection to form.
THE WITNESS: Counsel, let me make sure I understand your question.
You actually provide me on the screen more than 500 documents or papers?

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BY MR. NIGH:
Q. Yes.
A. In the PDF file format.
You're saying those files, you send it to the defendant lawyers; is that correct?
Q. No. I'm saying those files were sent to us in response to our deposition notice from your lawyers.
A. Yeah. Why that's my business? This is between you lawyers.
Q. My question to you is, you didn't review anywhere near 500 documents, correct?
MR. MERRELL: Objection to form.
THE WITNESS: It's not necessary for me to review over 500 documents. They are not relevant.
BY MR. NIGH:
Q. I understand. So you didn't rely on those documents as part of your expert opinion, correct? You didn't review them, you didn't rely on them,

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correct?
MR. MERRELL: Objection to form.
THE WITNESS: Wait a second. You're saying rely on any of this, or rely on some of this?
BY MR. NIGH:
Q. You didn't rely on over 500 documents to put together your expert report, because you didn't review them, correct?
A. I reviewed part of it. I didn't review the entire more than 500 documents.
Q. Right. So you wouldn't have relied on more than 500 documents if you didn't review more than 500 documents, correct?
A. That's correct.
Q. You understand that our request for documents was documents that you relied on or reviewed, correct?
A. I don't know. That's between you lawyers. I provide -- I

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provide on my side --
MR. NIGH: Let's pull up --
BY MR. NIGH:
Q. Sorry, I didn't mean to interrupt you.
MR. NIGH: Let's pull up LP-1600. It was marked Wei Exhibit 2, and let's go to Page 4. We can blow up those two requests again.
BY MR. NIGH:
Q. "Copies of any documents or articles relied upon" --
MR. NIGH: Let's underline the word "relied upon."
BY MR. NIGH:
Q. -- and, "Copies of any documents or articles reviewed."
MR. NIGH: Let's underline the word "reviewed."
BY MR. NIGH:
Q. Now, I think your statement is this is between the lawyers. I understand. What I'm asking -- my

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question to you is, in terms of Number 4 and Number 5, you didn't rely upon or review anywhere near 500 documents to draft your report, correct?
MR. MERRELL: Objection to form.
THE WITNESS: Yeah, that's correct.
MR. NIGH: Okay. Let's take this down.
BY MR. NIGH:
Q. Now, Doctor, you've mentioned many times that it's good for society to have higher quality studies conducted, and that we shouldn't rely on these other trashy studies.
Do you remember saying that?
MR. MERRELL: Objection to form.
THE WITNESS: I think I use junk papers, not trash.
BY MR. NIGH:
Q. Okay. My apologies. Let me ask that again.

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Doctor, you've mentioned many times that it's good for society to have higher quality studies conducted and that we shouldn't rely on these other junky papers, correct?
A. I said not other. Just some of the junk papers, if I remember correctly.
Q. Right. Didn't -- in response to my question about dietary studies and the Hidajat study, you would agree that all the dietary studies and the Hidajat study were junky papers, correct?
A. I didn't say that.
Q. You didn't say that?
A. No. I said in general, the society should not use junk paper to actually make a decision.
Q. Which dietary studies or Hidajat do you believe are not junk papers?
A. Say it again, sir?
Q. Which dietary studies or

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Hidajat do you believe are not junk papers?
A. Well, I have to go through all the papers again to tell you which is not very reliable, which one is good.
Q. Do you have some understanding now that there are some that were reliable?
A. I don't recall.
Q. You don't recall whether or not any of the dietary studies or Hidajat is reliable?
A. Well, I have to go back to the papers to answer your question, sir.
Q. My question to you is not each individual paper. My question to you is, do you recall whether any of the dietary studies or Hidajat, in your opinion, was reliable?
MR. MERRELL: Objection to form.
THE WITNESS: I have to go back to read the papers. If you can show me the paper, I will tell

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you which one is not in the standard we like to have it.
BY MR. NIGH:
Q. You understand that it's my turn to depose you here today. I don't have an obligation to show you every paper that you ask for. Do you understand that?
A. Oh, absolutely. I have every right to -- I have no opinion on your question. Do I have a right to say that?
Q. No. You have to answer my question.
My question to you is: Do you recall whether any of the dietary studies or Hidajat in your opinion was reliable? If you don't know, you can answer that way.
A. Okay. I don't know.
Q. So sitting here today, you don't know, in terms of your memory as, you know, what you've reviewed for your expert opinion here today, you don't know

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whether or not you would consider any of the dietary studies or the Hidajat study as reliable, correct?
MR. MERRELL: Objection to form.
THE WITNESS: Well, I can give you a couple examples, sir, which one I don't think is up to my standard or the society standard.
For example, the paper by L-O-H. Right. I said clearly in my report. And Dr. Loh used a Cox model with many, many baseline factors. And he used that Cox model to establish causation or association analysis.
And I didn't find a segment of the model fitting. I said it very clearly during the deposition. I said it very clearly in my report. Without a good solid assessment of the model fitting, I don't think I believe

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the results. That's the first one.

Second paper --

BY MR. NIGH:

Q. Go ahead.

A. Can I -- can I finish?

Q. You can. I'm not asking about what you feel was unreliable. My question --

A. You said reliable.

Q. Right.

A. You said reliable only. Reliable, that's the same thing, right? I'm give you some samples.

Q. Go ahead. You can give me some examples of what's unreliable in your opinion. That's fine, but it wasn't my question.

A. Z-H-E-N-G, the paper, his paper -- the study is a multiple regression model. He didn't provide a thorough model checking process. And I don't know how we can take his model and make a decision.

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And my question on many, many papers, I can sit down with you one by one, which one actually using modeling without a formal assessment of a model fitting.

That's my concern. You ask me without a model checking, do you believe this is reliable study or not.

In my opinion, they are not.

Q. Okay. My question to you is not the studies that you believe are unreliable. So let me start my question again.

So sitting here today, you don't know, in terms of your memory, as, you know, what you've reviewed for your expert opinion here today, you don't know whether or not you would consider any of the dietary studies or the Hidajat study as reliable, correct?

MR. MERRELL: Objection to form.

THE WITNESS: I don't think I can claim that any out of all

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those papers that I reviewed, they have a problem or which one is not up to the standard I like to see.

If you allow me to go through the papers, I'll be happy to tell you which one is reliable or not, right.

But if you're asking me do you think that any paper is reliable, I don't know.

BY MR. NIGH:

Q. In your expert report -- sorry. I didn't know you weren't done.

A. I don't report, sir. I know that you always -- sir, I'm sorry.

You always try to check my memory. I'm not quite sure that a deposition is a place to test a memory of the expert witness. That's my understanding for many years.

Now I'm not quite sure. Every time I'm asking you to help me to review the document or paper, you didn't even bother to show me the paper or

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document.

I don't understand why you don't allow me to review it and say what exactly I said either in my report or I'm talking to you in this deposition.

I wish I can be more accurate reflecting what I'm thinking instead of using my memory.

Q. Let's take a look at your report. It's in front of you. You've been allowed to use your expert report the entire time. It's marked Exhibit 3.

MR. NIGH: Let's pull it up. LP-1557.

BY MR. NIGH:

Q. Is it true that in your expert report, you do not mention a single dietary study or Hidajat as being reliable, correct?

A. I'm not for sure. So that wasn't my assignment to say which paper is reliable and which paper is not reliable. I use the totality of evidence across all the publications, and I make

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assessment to say in general, those studies support Dr. Madigan say in the report.

That's my assignment. I was not asked to please picking out some studies are reliable and which ones are not reliable. That was not my job.

Q. I understand.

You criticized many studies as being unreliable. And my question to you is: Can you find a single study in your report in terms of the dietary studies or occupational exposure studies that you state is reliable in your report?

MR. MERRELL: Objection to form.

THE WITNESS: Sitting here without review all the papers, I cannot answer your question, sir.

BY MR. NIGH:

Q. I'm asking you about your report, not the papers. Do you understand that your report, one of the

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purposes is to put the other side on notice of your opinions.

Do you understand that?

A. Yes.

Q. Can you point to me a single paper that you mentioned in your report, in terms of dietary studies or occupational exposure studies, that you stated is reliable?

A. Without a review of those papers, I cannot answer your question, sir.

Q. I'm asking you to review your report. In your report, do you mention a single dietary study or occupational exposure study that you find to be reliable?

I'm not talking about each individual paper. I'm talking about your expert report that's sitting in front of you, that you can take all the time you want to, to refresh your recollection, if you feel like that's what you need.

But do you see a single

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dietary study or occupational exposure study in your report that you state is reliable in your report?

A. Let me make sure I understand your question, sir. You're saying in my report, did I say anything among all the dietary occupational studies, which one is good paper, which one is a bad study?

Is that what you say?

Q. I just asked you -- let me -- let me help there.

I'm saying in your report, did you say anything among all the dietary and occupational exposure studies which one is good paper?

A. That was not my assignment, sir.

Q. So is that a no, because it wasn't your assignment?

A. No.

Q. You would agree with me that because you felt like that wasn't your assignment, you didn't say anything among

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all the dietary -- dietary or occupational exposure studies, which one was a good paper and reliable, correct?

A. I didn't say anything in my report which one is good. I did indicate some papers, and the majority of papers, including meta-analysis by Zui, by Song, I said it very clearly, sir.

We need to go back to each individual study in the meta-analysis, if they did a good job or not. If one of those studies didn't do a good job, that means the resulting meta-analysis paper wasn't very good either. That's what I said also in my deposition -- I'm sorry, in my report, right.

But I had to agree with you that I didn't say anything which study is acceptable, which one is good. I didn't say it clearly in my report.

Q. Okay. Now, Doctor, you're here on behalf of the defendant pharmaceutical companies, correct?

A. Yes, sir.

Q. And we've seen, you know, time and time again in the past that you have regularly represented defendant pharmaceutical companies, correct?

MR. MERRELL: Objection to form.

THE WITNESS: I'm not for sure on the so-called regularly, as often as Dr. Madigan helping the plaintiffs' side.

BY MR. NIGH:

Q. Doctor, you -- never mind. Strike that.

You understand that none of the defendant pharmaceutical companies that you're here on behalf of have attempted to measure the impact or effects that its NDMA-contaminated medications have had on people or the society, that they have not attempted to conduct their own study, correct?

MR. MERRELL: Objection to form.

THE WITNESS: I don't know,

sir. I have no data to say. I have no information about it. I have no idea.

BY MR. NIGH:

Q. Do you understand that none of the defendant pharmaceutical companies that you're on -- that you're here on behalf of have attempted to complete the sort of higher quality study that you've been discussing to measure the impact or effects that its NDMA-contaminated medications have had on people or the society, correct?

MR. MERRELL: Objection to form.

THE WITNESS: I have no idea on this, sir.

MR. NIGH: Okay. That's all the questions I have.

THE WITNESS: Thank you.

MR. MERRELL: Nothing here.

MR. NIGH: Thank you, Doctor. Appreciate your time.

THE WITNESS: See you later.

THE VIDEOGRAPHER: The time right now is 2:15 p.m. We are off the record.

(Excused.)

(Deposition concluded at approximately 2:15 p.m.)

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, LEE-JEN WEI, Ph.D., have the opportunity to read and sign the deposition transcript.

_____

MICHELLE L. GRAY,
A Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter and Notary Public
Dated: September 17, 2021

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Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, 402 - 570, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

LEE-JEN WEI, Ph.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

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Notary Public

LAWYER'S NOTES

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PAGE	LINE	CHANGE
26	17	Replace "physical" with "statistical"
REASON:		Transcription error
30	15	Delete "if"
REASON:		Transcription error
36	16	Replace "Hartley" with "Harkins"
REASON:		Transcription error
60	7	Replace "at" with "as"
REASON:		Transcription error
60	8	Replace "assigned" with "son is a"
REASON:		Transcription error
74	3	Replace "quantification" with "qualifications"
REASON:		Transcription error
92	24	Replace "backwards" with "back"
REASON:		Transcription error
126	18	Replace "if" with "for"
REASON:		Transcription error
131	11	Replace "models" with "problems"
REASON:		Transcription error
137	3	Replace "do" with "don't"
REASON:		Transcription error

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PAGE	LINE	CHANGE
140	7	Replace "want allow" with "want to allow for"
REASON:		Clarification
141	5	Replace "waiting" with "wanting"
REASON:		Transcription error
150	6	Replace "That" with "That's"
REASON:		Transcription error
152	7	Replace "at" with "as"
REASON:		Transcription error
154	7	Delete "smaller"
REASON:		Transcription error
154	14	Add ", what you're saying has some issues" after "valsartan"
REASON:		Clarification
157	16	Replace "tool" with "tools"
REASON:		Transcription error
159	15	Add "false" after "the"
REASON:		Clarification
160	8	Delete "point"
REASON:		Transcription error
160	15	Replace "talking it" with "popped"
REASON:		Transcription error

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PAGE	LINE	CHANGE
166	16	Delete "are"
REASON:		Transcription error
167	5	Replace "alteration" with "alternative"
REASON:		Transcription error
184	15	Replace "Jewel" with "Jewell"
REASON:		Clarification
184	17	Replace "Jewel" with "Jewell"
REASON:		Clarification
184	19	Replace "J-E-W-E-L" with "J-E-W-E-L-L"
REASON:		Clarification
201	10	Replace "safe" with "fair"
REASON:		Transcription error
217	19	Replace "ratio" with "threshold"
REASON:		Transcription error
218	8	Replace "essential" with "threshold"
REASON:		Transcription error
223	10	Delete "to"
REASON:		Transcription error
223	14	Replace "set" with "sets"
REASON:		Transcription error

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PAGE	LINE	CHANGE
224	19	Replace "Is" with "It is"
REASON:		Transcription error
234	9	Replace "topic" with "titles"
REASON:		Transcription error
256	14	Delete "is"
REASON:		Transcription error
258	16	Replace "to tally" with "totality of"
REASON:		Transcription error
260	10	Replace "rounding with "running in"
REASON:		Transcription
280	5	Replace "job and word" with "jargon word"
REASON:		Transcription error
217	19	Replace "ratio" with "threshold"
REASON:		Transcription error
290	5	Replace "immediate" with "median"
REASON:		Transcription error
292	12 & 13	Replace "this day" with "these days"
REASON:		Transcription error
293	8	Delete "to"
REASON:		Transcription error

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PAGE	LINE	CHANGE
298	3	Replace "pressing" with "impressive"
REASON:		Transcription error
299	4	Replace "experience" with "experienced"
REASON:		Transcription error
299	5	Replace "experience" with "experienced"
REASON:		Transcription error
310	24	Delete "the what"
REASON:		Transcription error
312	8	Replace "grow" with "blow"
REASON:		Transcription
312	9	Replace "grow" with "blow"
REASON:		Transcription error
315	13	Replace "affect" with "effect"
REASON:		Transcription error
351	18	Add ", the" after "be"
REASON:		Clarification
353	15	Replace "spec" with "specific covariates"
REASON:		Clarification
360	18	Replace "this date" with "these days"
REASON:		Transcription error

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PAGE	LINE	CHANGE
362	12	Replace "decisionmaking" with "decision-making"
REASON:		Transcription error
367	3	Replace "cubed" with "cubic"
REASON:		Transcription error
367	5	Replace "actions" with "interactions"
REASON:		Transcription error
368	4	Replacing "informing a" with "thing is informing the other"
REASON:		Clarification
369	6 & 7	Replace "this day" with "these days"
REASON:		Transcription
369	17	Delete though
REASON:		Transcription error
370	6	Replace "space" with "piece"
REASON:		Transcription error
374	1	Replace"Tanzeum" with "Avandia"
REASON:		Clarification
375	12	Replace "goes" with "does"
REASON:		Clarification
379	7	Replace "Largaucous" with "Lagakos"
REASON:		Transcription error

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PAGE	LINE	CHANGE
386	23	Replace "signal" with "simple"
REASON:		Transcription error
391	7	Replace "function" with "functions"
REASON:		Transcription error
391	10	Replace "function" with "functions"
REASON:		Transcription error
392	2	Replacing "limitation" with "patient"
REASON:		Transcription error
393	17	Replace "assess" with "sets"
REASON:		Transcription
REASON:		
REASON:		
REASON:		
REASON:		

ACKNOWLEDGMENT OF DEPONENT

I, Lee-Jen Wei, do hereby certify that I have read the foregoing pages, 1 - 401, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

LEE-JEN WEI, Ph.D. — DATE: Oct 15, 2021

Subscribed and sworn to before me this 15th day of October, 2021.

My commission expires:

Kimberly Harris
NOTARY PUBLIC
Forsyth County, GEORGIA
My Commission Expires February 6, 2024

Notary Public

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PAGE	LINE	CHANGE
61	24	Replace "row" with "role"
REASON:		Transcription error
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ACKNOWLEDGMENT OF DEPONENT

I, Lee-Jen Wei, do hereby certify that I have read the foregoing pages, 402 - 570, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

[signature] Oct 15, 2021

LEE-JEN WEI, Ph.D. DATE

Subscribed and sworn to before me this 15th day of October, 2021.

My commission expires: _____

Kimberly Harris
NOTARY PUBLIC
Forsyth County, GEORGIA
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[signature]

Notary Public